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The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

OFFICE OF GOVERNMENT ETHICS

5 CFR Part 2640

RIN 3209–AA09

Interpretation, Exemptions and Waiver Guidance Concerning the Federal Criminal Conflict of Interest Statute Prohibiting Acts Affecting a Personal Financial Interest; Amendment to Definition of "Employee"

AGENCY: Office of Government Ethics (OGE).

ACTION: Interim final rule with request for comments.

SUMMARY: The U.S. Office of Government Ethics is issuing this interim final rule to make a technical modification to the definition of "employee" in its regulations implementing the federal criminal conflict of interest statute concerning acts affecting a personal financial interest, in order to ensure their continued applicability to all individuals subject to requirements of the statute.

DATES: This interim regulation is effective September 6, 2016. Comments are invited and are due in writing by November 7, 2016.

ADDRESSES: You may submit comments, in writing, to OGE on this interim final rule, identified by RIN 3209–AA09, by any of the following methods:

E-Mail: usoge@oge.gov. Include the reference "Interpretation, Exemptions and Waiver Guidance Concerning 18 U.S.C. 208 (Acts Affecting A Personal Financial Interest); Amendment to Definition of 'Employee' " in the subject line of the message.

Fax: (202) 482–9237.

Mail/Hand Delivery/Courier: Office of Government Ethics, Suite 500, 1201 New York Avenue NW., Washington, DC 20005–3917, Attention: "Interpretation, Exemptions and Waiver Guidance Concerning 18 U.S.C. 208 (Acts Affecting A Personal Financial Interest); Amendment to Definition of 'Employee.' "

Instructions: All submissions must include OGE's agency name and the Regulation Identifier Number (RIN), 3209–AA09, for this rulemaking. All comments, including attachments and other supporting materials, will become part of the public record and be subject to public disclosure. Comments may be posted on OGE's Web site, *www.oge.gov.* Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments generally will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Christopher J. Swartz, Assistant Counsel, Office of Government Ethics, Suite 500, 1201 New York Avenue NW., Washington, DC 20005–3917; Telephone: 202–482–9300; TTY: 800–877–8339; Fax: 202–482–9237.

SUPPLEMENTARY INFORMATION:

I. Background

The U.S. Office of Government Ethics (OGE) is issuing this interim final rule making a technical modification to the definition of "employee" in its regulations implementing 18 U.S.C. 208. Section 208(a) prohibits participation in particular matters affecting a covered individual's personal and imputed financial interests. Section 208(b)(2) authorizes OGE to promulgate regulatory exemptions describing financial interests that are "too remote or too inconsequential" to warrant disqualification pursuant to section 208(a). Pursuant to 5 U.S.C. app. 402(b)(1) and Executive Order 12674 of April 12, 1989 (as modified by Executive Order 12731), OGE is responsible for providing uniform regulations interpreting section 208. In addition, section 208(d)(2) specifically directs OGE to adopt "uniform regulations for . . . exemptions" from the applicability of section 208(a). Consistent with these authorities, in 1996 OGE issued uniform regulations at 5 CFR part 2640 interpreting 18 U.S.C. 208 and establishing exemptions for all individuals subject to section 208(a). 61 FR 66830 (Dec. 18, 1996).

OGE established this uniform coverage by defining "employee" to mean "an officer or employee of the executive branch of the United States, or of any independent agency of the United States, a Federal Reserve bank director, officer, or employee, or an officer or employee of the District of Columbia," including "a special Government employee as defined in 18 U.S.C. 202." 5 CFR 2640.102(b). The language of this definition in 5 CFR part 2640 carefully covered all individuals then subject to the statute, including certain individuals who were not executive branch employees. *Compare id. with* 18 U.S.C. 208(a) (covering "an officer or employee of the executive branch of the United States Government, or of any independent agency of the United States, a Federal Reserve bank director, officer, or employee, or an officer or employee of the District of Columbia, including a special Government employee"). The applicability of 5 CFR part 2640 was, thus, coextensive with the applicability of section 208.

Recently, however, a cross-reference in the organic statute of a newly created board has expanded the coverage of the requirements of section 208 to include the board's members and staff, who would not otherwise be subject to section 208. Public Law 114–187, section 109(a) (2016). In order to ensure the continued applicability of 5 CFR part 2640 to all individuals subject to section 208, this interim regulation adds the phrase ". . . , or any other individual subject to requirements of 18 U.S.C. 208" at the end of the first sentence of the definition of "employee." This technical amendment will guard against uncertainty as to the applicability of 5 CFR part 2640 to the members and staff of this board, as well as to others who may in the future become subject to section 208. Prior to issuing this regulation, OGE consulted with the Office of Personnel Management and the Department of Justice, and pursuant to section 201(c) of Executive Order 12674, as modified by Executive Order 12731, has obtained the concurrence of the Department of Justice.

II. Matters of Regulatory Procedure

Administrative Procedure Act

Pursuant to sections 553(b) and 553(d)(3) of title 5 of the United States Code, the Director of the Office of Government Ethics has found good cause for dispensing with the usual requirements of notice and comment and a 30-day delay in the rule's effective date. Because this minor amendment is strictly technical in nature, providing notice and comment and delaying the effective date are unnecessary. Moreover, in clarifying the meaning of "employee," this rule is an interpretative rule and thus exempt from notice and comment and a delay in effective date pursuant to 5 U.S.C. 553(b) and 553(d)(2), respectively. Finally, this rule recognizes exemptions, which exempts the rule from the 30-day delayed effective date pursuant to 5 U.S.C. 553(d)(1). Nonetheless, this interim final rule provides a 60-day comment period for agencies and the public. The Office of Government Ethics will review any comments received during the comment period and consider any modifications to this rule that appear warranted.

Regulatory Flexibility Act

As Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this interim final rule would not have a significant economic impact on a substantial number of small entities because it primarily affects covered employees.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this regulation does not contain information collection requirements that require approval of the Office of Management and Budget.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 25, subchapter II), this interim final rule would not significantly or uniquely affect small governments and will not result in increased expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (as adjusted for inflation) in any one year.

Congressional Review Act

The Office of Government Ethics has determined that this rulemaking involves a nonmajor rule under the Congressional Review Act (5 U.S.C. chapter 8) and will, before the interim final rule takes effect, submit a report thereon to the U.S. Senate, House of Representatives and General Accounting Office in accordance with that law.

Executive Order 12866

In promulgating this rule amendment, the Office of Government Ethics has adhered to the regulatory philosophy and the applicable principles of regulation set forth in section 1 of Executive Order 12866, Regulatory Planning and Review. The Office of Management and Budget has determined that this technical rule amendment is not "significant" under Executive Order 12866.

Executive Order 12988

As Director of the Office of Government Ethics, I have reviewed this interim final rule in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

List of Subjects in 5 CFR Part 2640

Conflict of interests, Government employees.

Approved: August 30, 2016.

Walter M. Shaub, Jr.,

Director, Office of Government Ethics.

Accordingly, for the reasons set forth in the preamble, the Office of Government Ethics amends 5 CFR part 2640 as follows:

PART 2640—INTERPRETATION, EXEMPTIONS AND WAIVER GUIDANCE CONCERNING 18 U.S.C. 208 (ACTS AFFECTING A PERSONAL FINANCIAL INTEREST)

■ 1. The authority citation for part 2640 continues to read as follows:

Authority: 5 U.S.C. App. (Ethics in Government Act of 1978); 18 U.S.C. 208; E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

■ 2. Revise the first sentence of § 2640.102(b) to read as follows:

§ 2640.102 Definitions.

* * * * *

(b) *Employee* means an officer or employee of the executive branch of the United States, or of any independent agency of the United States, a Federal Reserve bank director, officer, or employee, an officer or employee of the District of Columbia, or any other individual subject to requirements of 18 U.S.C. 208. * * *

* * * * *

[FR Doc. 2016–21293 Filed 9–2–16; 8:45 am]

BILLING CODE 6345–03–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 171

[NRC–2015–0223]

RIN 3150–AJ66

Revision of Fee Schedules; Fee Recovery for Fiscal Year 2016; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; correcting amendment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) published a final rule amending regulations that became effective August 23, 2016. The fiscal year (FY) 2016 final fee rule, published June 24, 2016, amended the licensing, inspection, special project, and annual fees charged to NRC applicants and licensees. This document corrects the annual fee for materials licensees in the category "Nuclear laundries" from the FY 2016 rate of $0 to the FY 2015 rate of $40,100. This correction allows Agreement States to continue to collect fees in this fee category.

DATES: *Effective Date:* September 6, 2016.

ADDRESSES: Please refer to Docket ID NRC–2015–0223 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0223. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One

White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Michele Kaplan, Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–5256, email: *Michele.Kaplan@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC published a final rule amending regulations that became effective August 23, 2016. The FY 2016 final fee rule, published June 24, 2016 (81 FR 41171), amended the licensing, inspection, special project, and annual fees charged to NRC applicants and licensees.

Fee category 6.A. under § 171.16(d) includes fees for licenses for the commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material [Program Code(s): 03218]. Because the NRC has no licensees in this category, the final rule inadvertently set the fee amount at $0. However, there are several Agreement States with licensees in this category. Agreement States that regulate nuclear laundries incorporate by reference the NRC fee schedule into their own regulations to establish their fees. To establish a fee for nuclear laundries in the absence of an NRC fee amount, the Agreement States would need to initiate a rulemaking, a timely and costly solution to fix the NRC's administrative oversight. Therefore, the NRC is correcting this oversight and changing the annual fee for fee category 6.A. for materials licensees from the FY 2016 rate of $0 to the FY 2015 rate of $40,100. This correction will have no material impact on the fees paid by NRC licensees for services; it will, however, allow Agreement States to continue to set and collect fees for regulated services in the equivalent fee category.

Rulemaking Procedure

Under the Administrative Procedure Act (5 U.S.C. 553(b)), an agency may waive the normal notice and comment requirements if it finds, for good cause, that they are impracticable, unnecessary, or contrary to the public interest. As authorized by 5 U.S.C. 553(b)(3)(B), the NRC finds good cause to waive notice and opportunity for comment on this amendment. This amendment is needed to correct an inadvertent error by the NRC, which removed the fee amount for nuclear laundries. The NRC incorrectly believed that there would be no consequences to removing the fee amount because there are no NRC-regulated nuclear laundries for which the NRC must collect fees. However, the NRC did not realize that many Agreement States regulating nuclear laundries base their fees upon the NRC-prescribed amount. Removal of the NRC fee would have the unforeseen and unintended adverse consequence of preventing those Agreement States from collecting fees from nuclear laundries regulated by those Agreement States. This rulemaking merely restores the previously prescribed fee for NRC-regulated nuclear laundries. The sole purpose of this rulemaking is to allow those Agreement States that base their fees on the NRC-prescribed amount to collect fees from nuclear laundries regulated by those Agreement States. As set forth earlier, this action has no effect on NRC-regulated entities because there are no NRC-regulated nuclear laundries. For these reasons, the NRC finds, pursuant to 5 U.S.C. 553(d)(3), that good cause exists to make this rule effective upon publication of this notice.

List of Subjects in 10 CFR Part 171

Annual charges, Approvals, Byproduct material, Holders of certificates, Intergovernmental relations, Nonpayment penalties, Nuclear materials, Nuclear power plants and reactors, Registrations, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 171:

PART 171—ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

■ 1. The authority citation for part 171 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w), 223, 234 (42 U.S.C. 2014, 2201(w), 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2214; 44 U.S.C. 3504 note.

■ 2. In § 171.16, paragraph (d), revise fee category 6.A. of the table to read as follows:

§ 171.16 Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC.

* * * * *

(d) * * *

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC

[See footnotes at end of table]

Category of materials licenses	Annual fees[1][2][3]
* * * * * *	*
6. Nuclear laundries:.	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material [Program Code(s): 03218]	$40,100
* * * * * *	*

---

[1] Annual fees will be assessed based on whether a licensee held a valid license with the NRC authorizing possession and use of radioactive material during the current FY. The annual fee is waived for those materials licenses and holders of certificates, registrations, and approvals who either filed for termination of their licenses or approvals or filed for possession only/storage licenses before October 1, 2015, and permanently ceased licensed activities entirely before this date. Annual fees for licensees who filed for termination of a license, downgrade of a license, or for a possession-only license during the FY and for new licenses issued during the FY will be prorated in accordance with the provisions of § 171.17. If a person holds more than one license, certificate, registration, or approval, the annual fee(s) will be assessed for each license, certificate, registration, or approval held by that person. For licenses that authorize more than one activity on a single license (*e.g.,* human use and irradiator activities), annual fees will be assessed for each category applicable to the license.

[2] Payment of the prescribed annual fee does not automatically renew the license, certificate, registration, or approval for which the fee is paid. Renewal applications must be filed in accordance with the requirements of parts 30, 40, 70, 71, 72, or 76 of this chapter.

[3] Each FY, fees for these materials licenses will be calculated and assessed in accordance with § 171.13 and will be published in the **Federal Register** for notice and comment.

* * * * *

Dated at Rockville, Maryland, this 30th day of August, 2016.

For the Nuclear Regulatory Commission.

Cindy Bladey,

Chief, Rules, Announcements and Directives Branch, Division of Administrative Services, Office of Administration.

[FR Doc. 2016–21270 Filed 9–2–16; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8989; Directorate Identifier 2016–CE–025–AD; Amendment 39–18641; AD 2016–17–04 R1]

RIN 2120–AA64

Airworthiness Directives; All Hot Air Balloons

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are revising Airworthiness Directive (AD) 2016–17–04, which applies to all hot air balloons equipped with BALÓNY KUBÍČEK spol. s r.o. Model Kubíček burners. Both the original and revised AD result from mandatory continuing airworthiness information (MCAI) issued by the aviation authority of another country to identify and correct an unsafe condition on an aviation product. This AD action revises AD 2016–17–04 to eliminate certain unnecessary documentation requirements.

DATES: This AD is effective on September 6, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 29, 2016 (81 FR 57449, August 23, 2016).

We must receive comments on this AD by October 21, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this AD, contact BALÓNY KUBÍČEK spol. s r. o., Jarní 2a, 614 00 Brno, Czech Republic, telephone: +420 545 422 620; fax: +420 545 422 621; email: *info@kubicekballons.cz;* Internet: *http://www.kubicekballoons.eu.* You may view this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the Internet at *http://www.regulations.gov* by searching for locating Docket No. FAA–2016–8989.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8989; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4123; fax: (816) 329–4090; email: *karl.schletzbaum@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On August 16, 2016, we issued AD 2016–17–04, Amendment 39–18617 (81 FR 57449, August 23, 2016). That AD required actions intended to address an unsafe condition on all hot air balloons equipped with a Kubíček burner and was based on mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country. That MCAI states:

> Three propane leaks were reported in the recent past on a burner manufactured by Balóny Kubíček spol. s.r.o., equipped with the fuel hoses made of hose material "EGEFLEX".
>
> This condition, if not detected and corrected, could result in a fire, damaging the balloon and its envelope, ultimately leading to an emergency landing, with consequent injury to balloon occupants and persons on the ground.
>
> To address this potential unsafe condition, Balóny Kubíček spol. s.r.o. (the hose assemblies' manufacturer) published Service Bulletin (SB) N° BB/50, BB–S/11, AB24 rev. 1, which provides instructions for replacement of the affected fuel hoses with an improved part. As the affected burner and related fuel hoses can easily be installed on other hot air balloons, this AD applies to all possibly affected type designs.
>
> For the reasons described above, this AD required identification and replacement of the affected fuel hoses.

You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8989.

Since we issued AD 2016–17–04, Amendment 39–18617 (81 FR 57449, August 23, 2016), we have determined that the AD should be revised to eliminate the unnecessary need to document the AD by logbook entry when the hot air balloon does not have fuel hoses made of "EGEFLEX" material. Therefore, the FAA determined that the inspection required should be eliminated and the applicability should be narrowed to only include those balloons that have both the Kubíček burner and fuel hoses made of "EGEFLEX" material installed.

Related Service Information Under 1 CFR Part 51

BALÓNY KUBÍČEK spol. s r.o. has issued Service Bulletin No. BB/50, BB–S/11, AB24 rev.1, dated May 12, 2016. The service information describes procedures for replacing all fuel hoses on burners that are made of "EGEFLEX" material. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this AD.

FAA's Determination and Requirements of This AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are issuing this AD because we evaluated all information provided by the State of

Design Authority and determined the unsafe condition exists and is likely to exist or develop on type certificated products that incorporate the affected burners.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because this condition could result in a fire, damaging the balloon and its envelope, ultimately leading to an emergency landing, with consequent injury to the occupants and persons on the ground. Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–8989; Directorate Identifier 2016–CE–025–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this AD.

Costs of Compliance

We estimate that this AD will affect 60 products of U.S. registry. We also estimate that it will take about 2 work-hours per product to comply with the replacement requirement of this AD. The average labor rate is $85 per work-hour. Parts cost is about $200 per product.

Based on these figures, we estimate the cost of this AD on U.S. operators to be $22,200, or $ 370 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing AD 2016–17–04, Amendment 39–18617 (81 FR 57449, August 23, 2016), and adding the following new AD:

2016–17–04 R1 ALL HOT AIR BALLOONS: Amendment 39–18641; Docket No. FAA–2016–8989; Directorate Identifier 2016–CE–025–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective on September 6, 2016.

(b) Affected ADs

This AD replaces AD 2016–17–04, Amendment 39–18617 (81 FR 57449, August 23, 2016) ("AD 2016–17–04").

(c) Applicability

This AD applies to all hot air balloons, certificated in any category, that are equipped with all of the following:

(1) a BALÓNY KUBÍČEK spol. s r.o. Model Kubíček burner; and

(2) fuel hose(s) made of "EGEFLEX" material.

(d) Subject

Air Transport Association of America (ATA) Code 28: Fuel.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) issued by the aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as propane leaks on burners equipped with fuel hoses made of "EGEFLEX" material. We are issuing this AD to prevent propane leaks in the fuel hoses, which could result in a fire, damaging the balloon and its envelope, ultimately leading to an emergency landing, with consequent injury to the occupants and persons on the ground. This AD action revises AD 2016–17–04 to eliminate the unnecessary need to document the AD by logbook entry when the hot air balloon does not have fuel hoses made of "EGEFLEX" material. This is done by eliminating the inspection required and narrowing the applicability to only include those balloons that have both the Kubíček burner and fuel hoses made of "EGEFLEX" material.

(f) Actions and Compliance

Unless already done, no later than September 12, 2016 (this date is 14 days after August 29, 2016, which was the effective date of AD 2016–17–04), replace any fuel hose made of "EGEFLEX" material following BALÓNY KUBÍČEK spol. s r.o. Service Bulletin No. BB/50, BB–S/11, AB24 rev.1, dated May 12, 2016.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4123; fax: (816)

329–4090; email: *karl.schletzbaum@faa.gov.* Before using any approved AMOC on any balloon to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(h) Special Flight Permit

Special flight permits are prohibited.

(i) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No. 2016–0151, dated July 26, 2016, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8989.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on August 29, 2016 (81 FR 57449, August 23, 2016).

(i) BALÓNY KUBÍČEK spol. s r.o. Service Bulletin No. BB/50, BB–S/11, AB24 rev.1, dated May 12, 2016.

(ii) Reserved.

(4) For BALÓNY KUBÍČEK spol. s r.o. service information identified in this AD, contact BALÓNY KUBÍČEK spol. s r. o., Jarní 2a, 614 00 Brno, Czech Republic, telephone: +420 545 422 620; fax: +420 545 422 621; email: *info@kubicekballons.cz.* Internet: *http://www.kubicekballoons.eu.*

(5) You may view this service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the Internet at *http://www.regulations.gov* by searching for locating Docket No. FAA–2016–8989.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Kansas City, Missouri, on August 30, 2016.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–21409 Filed 9–2–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 748

[Docket No. 160810722–6722–01]

RIN 0694–AH05

Amendments to Existing Validated End-User Authorization in the People's Republic of China: Boeing Tianjin Composites Co. Ltd.

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to revise the existing Validated End-User (VEU) list for the People's Republic of China (PRC) by updating the list of eligible destinations (facilities) for VEU Boeing Tianjin Composites Co. Ltd. (BTC). Specifically, BIS amends supplement No. 7 to part 748 of the EAR to change the written address of BTC's existing facility. The physical location of the facility has not changed. BIS updated the facility address after receiving notification of the change from BTC. The End-User Review Committee reviewed and authorized the amendment in accordance with established procedures. The updated address contributes to maintaining accurate location information for BTC's VEU.

DATES: This rule is effective September 6, 2016.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, U.S. Department of Commerce, Phone: 202–482–5991; Email: *ERC@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

Authorization Validated End-User

Validated End-Users (VEUs) are designated entities located in eligible destinations to which eligible items may be exported, reexported, or transferred (in-country) under a general authorization instead of a license. The names of the VEUs, as well as the dates they were so designated, and their respective eligible destinations (facilities) and items are identified in supplement No. 7 to part 748 of the EAR. Under the terms described in that supplement, VEUs may obtain eligible items without an export license from BIS, in conformity with § 748.15 of the EAR. Eligible items vary between VEUs and may include commodities, software, and technology, except those controlled for missile technology or crime control reasons on the Commerce Control List (CCL) (part 774 of the EAR).

VEUs are reviewed and approved by the U.S. Government in accordance with the provisions of § 748.15 and supplement Nos. 8 and 9 to part 748 of the EAR. The End-User Review Committee (ERC), composed of representatives from the Departments of State, Defense, Energy, Commerce, and other agencies as appropriate, is responsible for administering the VEU program. BIS amended the EAR in a final rule published on June 19, 2007 (72 FR 33646), to create Authorization VEU.

Amendment to Existing VEU Authorization for Boeing Tianjin Composites Co. Ltd. (BTC) in the People's Republic of China

Revision to the List of "Eligible Destinations" for BTC

In this rule, BIS amends supplement No. 7 to part 748 to revise BTC's VEU authorization. Specifically, in this rule, BIS updates the written address of BTC's facility in the People's Republic of China to which the company's eligible items may be exported, reexported or transferred (in-country). The physical location of the facility has not changed.

The amendment to the address of BTC's facility is in response to a request from BTC. This amendment was approved by the ERC. The revision is as follows:

Revision to Address of BTC's Eligible Destination (Facility)

Current address: Boeing Tianjin Composites Co. Ltd., No. 4–388 Hebei Road, Tanggu Tianjin, China.

New address: Boeing Tianjin Composites Co. Ltd., 4566 Hebei Road, Marine Hi-Tech Development Area, Tanggu District, Tianjin, China 300451.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 4, 2016, 81 FR 52587 (August 8, 2016), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. This rule involves collections previously approved by the Office of Management and Budget (OMB) under Control Number 0694–0088, "Multi-Purpose Application," which carries a burden hour estimate of 43.8 minutes to prepare and submit form BIS–748; and for recordkeeping, reporting and review requirements in connection with Authorization VEU, which carries an estimated burden of 30 minutes per submission. This rule is expected to result in a decrease in license applications submitted to BIS. Total burden hours associated with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) and OMB Control Number 0694–0088 are not expected to increase significantly as a result of this rule. Notwithstanding any other provisions of law, no person is required to respond to, nor be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. Pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), BIS finds good cause to waive the otherwise applicable requirement that this rule be subject to notice and the opportunity for public comment because it is unnecessary. In determining whether to grant VEU designations, a committee of U.S. Government agencies evaluates information about and commitments made by candidate companies, the nature and terms of which are set forth in 15 CFR part 748, supplement No. 8. The criteria for evaluation by the committee are set forth in 15 CFR 748.15(a)(2). The information, commitments, and criteria for this extensive review were all established through the notice of proposed rulemaking and public comment process (71 FR 38313 (July 6, 2006) (proposed rule), and 72 FR 33646 (June 19, 2007) (final rule)). Given the similarities between the authorizations provided under the VEU program and export licenses (as discussed further below), the publication of this information does not establish new policy. In publishing this final rule, BIS amends the authorization for an existing eligible VEU to update the address of the eligible destination (facility). This change has been made within the established regulatory framework of the VEU program. Further, this rule does not abridge the rights of the public or eliminate the public's option to export under any of the forms of authorization set forth in the EAR.

Publication of this rule in other than final form is unnecessary because the authorizations granted in the rule are consistent with the authorizations granted to exporters for individual licenses (and amendments or revisions thereof), which do not undergo public review. In addition, as with license applications, VEU authorization applications contain confidential business information, which is necessary for the extensive review conducted by the U.S. Government in assessing such applications. This information is extensively reviewed according to the criteria for VEU authorizations, as set out in 15 CFR 748.15(a)(2). Additionally, just as license applications are reviewed through an interagency review process, the authorizations granted under the VEU program involve interagency deliberation and result from review of public and non-public sources, including licensing data, and the measurement of such information against the VEU authorization criteria. Given the nature of the review, and in light of the parallels between the VEU application review process and the review of license applications, public comment on this authorization and subsequent amendments prior to publication is unnecessary. Moreover, because, as noted above, the criteria and process for authorizing and administering VEUs were developed with public comments, allowing additional public comment on this amendment to individual VEU authorizations, which was determined according to those criteria, is unnecessary.

Section 553(d) of the APA generally provides that rules may not take effect earlier than thirty (30) days after they are published in the **Federal Register**. However, BIS finds good cause to waive the 30-day delay in effectiveness for this rule pursuant to 5 U.S.C. 553(d)(3) because the delay would be contrary to the public interest. BIS is simply amending the authorization of an existing VEU to update the address of the eligible destination (facility). BIS amends the EAR in this rule consistent with established objectives and parameters administered and enforced by the responsible designated departmental representatives to the End-User Review Committee. Delaying this action's effectiveness would likely cause confusion regarding which items are authorized by the U.S. Government to be shipped to which eligible destination (facility), which would stifle the purpose of the VEU Program. Accordingly, it is contrary to the public interest to delay this rule's effectiveness.

No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required under the APA or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. As a result, no final regulatory flexibility analysis is required and none has been prepared.

List of Subjects in 15 CFR Part 748

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

Accordingly, part 748 of the EAR (15 CFR parts 730–774) is amended as follows:

PART 748—[AMENDED]

■ 1. The authority citation for part 748 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 4, 2016, 81 FR 52587 (August 8, 2016).

■ 2. Amend supplement No. 7 to part 748 by revising the entry for "Boeing Tianjin Composites Co. Ltd." in "China (People's Republic of)" to read as follows:

SUPPLEMENT NO. 7 TO PART 748—AUTHORIZATION VALIDATED END-USER (VEU): LIST OF VALIDATED END-USERS, RESPECTIVE ITEMS ELIGIBLE FOR EXPORT, REEXPORT AND TRANSFER, AND ELIGIBLE DESTINATIONS

Country	Validated end-user	Eligible items (by ECCN)	Eligible destination	**Federal Register** citation
Nothing in this Supplement shall be deemed to supersede other provisions in the EAR, including but not limited to § 748.15(c).				
*	*	*	*	*
	Boeing Tianjin Composites Co. Ltd.	1B001.f, 1D001 (limited to "software" specially designed or modified for the "use" of equipment controlled by 1B001.f), 2B001.b.2 (limited to machine tools with accuracies no better than (*i.e.,* not less than) 13 microns), 2D001 (limited to "software," other than that controlled by 2D002, specially designed or modified for the "use" of equipment controlled by 2B001.b.2), and 2D002 (limited to "software" for electronic devices, even when residing in an electronic device or system, enabling such devices or systems to function as a "numerical control" unit, capable of coordinating simultaneously more than 4 axes for "contouring control" controlled by 2B001.b.2).	Boeing Tianjin Composites Co. Ltd., 4566 Hebei Road, Marine Hi-Tech Development Area, Tanggu District, Tianjin, China 300451.	72 FR 59164, 10/19/07. 74 FR 19382, 4/29/09. 77 FR 10953, 2/24/12. 77 FR 40258, 7/9/12. 81 FR [INSERT PAGE NUMBER], September 6, 2016.
*	*	*	*	*

Dated: August 30, 2016.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2016–21333 Filed 9–2–16; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. FDA–1975–N–0012; Formerly Part of Docket No. 1975N–0183H]

RIN 0910–AF69

Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is issuing this final rule establishing that certain active ingredients used in over-the-counter (OTC) consumer antiseptic products intended for use with water (referred to throughout this document as consumer antiseptic washes) are not generally recognized as safe and effective (GRAS/GRAE) and are misbranded. FDA is issuing this final rule after considering the recommendations of the Nonprescription Drugs Advisory Committee (NDAC); public comments on the Agency's notices of proposed rulemaking; and all data and information on OTC consumer antiseptic wash products that have come to the Agency's attention. This final rule amends the 1994 tentative final monograph (TFM) for OTC antiseptic drug products that published in the **Federal Register** of June 17, 1994 (the 1994 TFM). The final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: This rule is effective September 6, 2017.

ADDRESSES: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Pranvera Ikonomi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5418, Silver Spring, MD 20993–0002, 240–402–0272.

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Executive Summary

Purpose of the Final Rule

This final rule finalizes the consumer antiseptic wash proposed rule published in the **Federal Register** of December 17, 2013 (78 FR 76444) (2013 Consumer Wash Proposed Rule (PR)) and amends the 1994 TFM for OTC antiseptic drug products that published in the **Federal Register** of June 17, 1994 (59 FR 31402). The amendment is part of FDA's ongoing rulemaking to evaluate the safety and effectiveness of OTC drug products marketed in the United States on or before May 1972 (OTC Drug Review). This final rule applies to consumer antiseptic wash products that are intended for use with water and are rinsed off after use, including hand washes and body washes.

In response to several comments submitted to the 2013 Consumer Wash PR, FDA has deferred further rulemaking on three specific active ingredients used in OTC consumer antiseptic wash products to allow for the development and submission of new safety and effectiveness data to the record for these ingredients. The deferred active ingredients are benzalkonium chloride, benzethonium chloride, and chloroxylenol. Accordingly, FDA does not make a determination of general recognition of safety and effectiveness for these three active ingredients in this final rule. The monograph or new drug status of these three ingredients will be addressed either after completion and analysis of ongoing studies to address the safety and efficacy data gaps of these ingredients or at a later date if these studies are not completed.

With the exception of the three deferred consumer antiseptic wash active ingredients, this rulemaking finalizes the nonmonograph status of the remaining 19 active ingredients intended for use in consumer antiseptic washes identified in the 2013 Consumer Wash PR. As explained, either no additional data were submitted or the data and information that were submitted were not sufficient to support monograph conditions for these 19 consumer antiseptic wash ingredients. Therefore, with the exception of the three deferred consumer antiseptic wash active ingredients, this rule finalizes the 2013 Consumer Wash PR, which proposed amending the 1994 TFM, with the remaining 19 consumer antiseptic wash active ingredients found to be not GRAS/GRAE. Accordingly, these 19 consumer antiseptic wash drug products are misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352) and are new drugs under section 201(p) of the FD&C Act (21 U.S.C. 321(p)) for which approved applications under section 505 of the FD&C Act (21 U.S.C. 355) and part 314 (21 CFR part 314) of the regulations are required for marketing.

In separate rulemakings, we are proposing conditions under which OTC consumer antiseptic rubs (products that are not rinsed off after use, including hand rubs and antibacterial wipes) (81 FR 42912, June 30, 2016) and OTC antiseptics intended for use by health care professionals in a hospital setting or other health care situation outside the hospital (80 FR 25166, May 1, 2015) are GRAS/GRAE. Accordingly, this final rule covers only OTC consumer antiseptic washes that are intended for use as either a hand wash or a body wash, and does not cover health care antiseptics (80 FR 25166), consumer antiseptic rubs (81 FR 42912), antiseptics identified as "first aid antiseptics" in the 1991 First Aid TFM (56 FR 33644), or antiseptics used by the food industry. Those antiseptic products are not addressed in this final rule.

Summary of the Major Provisions of the Final Rule

A. Effectiveness

As explained in the 2013 Consumer Wash PR, a determination that an active ingredient is GRAS/GRAE for a particular intended use requires a benefit-to-risk assessment for that particular use of the ingredient. If the active ingredient in a drug product carries the potential risk associated with the drug (*e.g.,* reproductive toxicity or carcinogenicity), but does not provide a clinical benefit, then the benefit-to-risk calculation shifts towards a not GRAS/GRAE status for that drug. New information on potential risks posed by the use of certain consumer antiseptic washes prompted us to reevaluate the data needed for classifying consumer antiseptic wash active ingredients as generally recognized as effective (GRAE). As a result, we proposed that the risk from the use of a consumer antiseptic wash drug product must be balanced by a demonstration—through studies that demonstrate a direct clinical benefit (*i.e.,* a reduction of infection)—that the product is superior to washing with nonantibacterial soap and water in reducing infection (78 FR 76444 at 76450).

We have considered the recommendations from the public meetings held by the Agency on antiseptics (see section II.B, table 2) and evaluated the available literature, as well as the data, the comments, and other information that were submitted to the rulemaking on the effectiveness of the consumer antiseptic wash active ingredients addressed in this final rule. The data and information submitted for these active ingredients are insufficient to demonstrate that there is any additional benefit from the use of these active ingredients in consumer antiseptic wash products compared to nonantibacterial soap and water. Consequently, the available data do not support a GRAE determination for these consumer antiseptic wash active ingredients.

B. Safety

As explained in the 2013 Consumer Wash PR, several important scientific developments that affect the safety evaluation of consumer antiseptic wash active ingredients have occurred since FDA's 1994 evaluation of the safety of consumer antiseptic active ingredients under the OTC Drug Review. New data suggests that the systemic exposure to these active ingredients is higher than previously thought, and new information about the potential risks from systemic absorption and long-term exposure is now available. New safety information also suggests that widespread antiseptic use could have an impact on the development of bacterial resistance. To support a classification of generally recognized as safe (GRAS) for consumer antiseptic wash active ingredients, we proposed that additional data was needed to demonstrate that those ingredients meet current safety standards (78 FR 76444 at 76453 to 76458).

The minimum data needed to demonstrate safety for all consumer antiseptic wash active ingredients falls into three broad categories: (1) Safety data studies described in current FDA guidance (*e.g.,* nonclinical and human pharmacokinetic studies, developmental and reproductive toxicity studies, and carcinogenicity studies); (2) data to characterize potential hormonal effects; and (3) data to evaluate the development of bacterial resistance.

We have considered the recommendations from the public meetings held by the Agency on antiseptics (see section II.B, table 2) and evaluated the available literature, as well as the data, the comments, and other information that were submitted to the rulemaking on the safety of consumer antiseptic wash active ingredients addressed in this final rule. The available information and published data for the 19 active ingredients considered in this final rule are insufficient to establish the safety of long-term, daily repeated exposure to these active ingredients used in consumer wash products. Consequently, the available data do not support a GRAS determination for the consumer antiseptic wash active ingredients included in this rule.

C. Costs and Benefits

This final rule establishes that 19 active ingredients, including triclosan and triclocarban, are not GRAS/GRAE and consumer antiseptic wash products containing these ingredients are misbranded for use in consumer antiseptic washes. Regulatory action is being deferred on three active ingredients that were included in the proposed rule: Benzalkonium chloride, benzethonium chloride, and chloroxylenol. The primary estimated benefits come from reduced exposure to antiseptic active ingredients by 2.2 million pounds per year. Limitations in the available data characterizing the health effects resulting from widespread long-term exposure to these ingredients prevent us from translating the estimated reduced exposure into monetary equivalents of health effects. The primary estimate of costs annualized over 10 years is approximately $23.6 million at a 3 percent discount rate and $27.6 million at a 7 percent discount rate. These costs consist of total one-time costs of relabeling and reformulation ranging from $106.3 to $402.8 million. Under the final rule, we estimate that each pound of reduced exposure to antiseptic active ingredients will cost $12.97 to $14.28 at a 3 percent discount rate and $16.36 to $18.02 at a 7 percent discount rate.

Summary of the costs and benefits of the final rule	Total benefits	Total costs annualized over 10 years (in millions)	Total one-time costs (in millions)
Total	Reduced exposure to antiseptic ingredients by 2.2 million pounds annually.	$23.6 (at 3%) $27.6 (at 7%)	$106.3 to $402.8.

I. Introduction

In the following sections, we provide a brief description of terminology used in the OTC Drug Review regulations, an overview of OTC topical antiseptic drug products, and a more detailed description of the OTC consumer antiseptic wash active ingredients that are the subject of this final rule.

A. Terminology Used in the OTC Drug Review Regulations

1. Proposed, Tentative Final, and Final Monographs

To conform to terminology used in the OTC Drug Review regulations (§ 330.10 (21 CFR 330.10)), the advance notice of proposed rulemaking that was published in the **Federal Register** of September 13, 1974 (39 FR 33103) (1974 ANPR), was designated as a "proposed monograph." Similarly, the notices of proposed rulemaking, which were published in the **Federal Register** of January 6, 1978 (43 FR 1210) (1978 TFM), the **Federal Register** of June 17, 1994 (59 FR 31402) (1994 TFM), and the **Federal Register** of December 17, 2013 (78 FR 76444) (2013 Consumer Wash PR) were each designated as a TFM (see table 1 in section II.A).

2. Category I, II, and III Classifications

The OTC drug procedural regulations in § 330.10 use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required). Section 330.10 provides that any testing necessary to resolve the safety or effectiveness issues that resulted in an initial Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph (*i.e.*, a final rule or regulation). Therefore, the proposed rules (at the tentative final monograph stage) used the concepts of Categories I, II, and III.

At this final monograph stage, FDA does not use the terms "Category I," "Category II," and "Category III." In place of Category I, the term "monograph conditions" is used; in place of Categories II and III, the term "nonmonograph conditions" is used.

B. Topical Antiseptics

The OTC topical antimicrobial rulemaking has had a broad scope, encompassing drug products that may contain the same active ingredients, but that are labeled and marketed for different intended uses. The 1974 ANPR for topical antimicrobial products encompassed products for both health care and consumer use (39 FR 33103). The ANPR covered seven different intended uses for these products: (1) Antimicrobial soap; (2) healthcare personnel hand wash; (3) patient preoperative skin preparation; (4) skin antiseptic; (5) skin wound cleanser; (6) skin wound protectant; and (7) surgical hand scrub (39 FR 33103 at 33140). FDA subsequently identified skin antiseptics, skin wound cleansers, and skin wound protectants as antiseptics used primarily by consumers for first aid use and referred to them collectively as "first aid antiseptics." We published a separate TFM covering first aid antiseptics in the **Federal Register** of July 22, 1991 (56 FR 33644). In section III.E, we address comments filed in this rulemaking related to first aid antiseptics, but we do not otherwise discuss first aid antiseptics further in this document. This final rule does not have an impact on the monograph status of first aid antiseptics.

The four remaining categories of topical antimicrobials were addressed in the 1994 TFM (59 FR 31402). The 1994 TFM covered: (1) Antiseptic hand wash (*i.e.*, consumer hand wash); (2) health care personnel hand wash; (3) patient preoperative skin preparation; and (4) surgical hand scrub (59 FR 31402 at 31442). This final rule does not have an impact on the monograph status of health care personnel hand washes, patient preoperative skin preparations, or surgical hand scrubs. In the 1994 TFM, FDA also identified a new category of antiseptics for use by the food industry and requested relevant data and information (59 FR 31402 at 31440). In section III.B.4, we address comments filed in this rulemaking on antiseptics for use by the food industry, but we do not otherwise further discuss these antiseptics in this document. This final rule does not have an impact on the monograph status of antiseptics for food industry use.

In the 2013 Consumer Wash PR, we proposed that our evaluation of OTC antiseptic drug products be further subdivided into health care antiseptics and consumer antiseptics (78 FR 76444 at 76446). These categories are distinct based on the proposed use setting, target population, and the fact that each setting presents a different risk for infection. In the 2013 Consumer Wash PR (78 FR 76444 at 76446 to 76447) and the consumer antiseptic rub proposed rule published in the **Federal Register** of June 30, 2016 (81 FR 42912) (2016 Consumer Rub PR), we proposed that our evaluation of OTC consumer antiseptic drug products be further subdivided into consumer washes (products that are rinsed off with water, including hand washes and body washes) and consumer rubs (products that are not rinsed off after use, including hand rubs and antibacterial wipes) (78 FR 764444 at 76447). Consumer antiseptic wash products are intended to be used when soap and water are available, whereas, consumer antiseptic rub products are intended to be used when soap and water are unavailable, and thus, are left on and not rinsed off. To account for the differences between consumer washes and consumer rubs, the safety and effectiveness of the active ingredients are being evaluated for each intended use separately. This final rule does not have an impact on the monograph status of consumer antiseptic rub products.

C. This Final Rule Only Covers Consumer Antiseptic Washes

We refer to the group of products covered by this final rule as "consumer antiseptic washes." Consumer antiseptic washes include a variety of personal care products intended to be used with water, such as antibacterial soaps, hand washes, and antibacterial body washes. As discussed further in section III.B.3, these products may be used by consumers for personal use in the home and public settings on a frequent, daily basis. In the United States consumer setting, where the target population is composed of generally healthy individuals, the risk of infection and the scope of the spread of infection is relatively low compared to the health care setting, where patients are generally more susceptible to infection and the potential for spread of infection is high.

This final rule covers only OTC consumer antiseptic washes that are intended for use as either a hand wash or a body wash, but that are not identified as "first aid antiseptics" in the 1991 First Aid TFM (56 FR 33644), health care antiseptics (80 FR 25166), consumer antiseptic rubs (81 FR 42912), or antiseptics used by the food industry. The distinctions between consumer washes and rubs, and between consumer hand washes and body washes are discussed in detail in the 2013 Consumer Wash PR (78 FR at 76446 to 76447) and the 2016 Consumer Rub PR (81 FR 42912). Completion of the monograph for Consumer Antiseptic Wash Products and certain other monographs for the active ingredient triclosan is subject to a Consent Decree entered by the U.S. District Court for the Southern District of New York on November 21, 2013, in *Natural Resources Defense Council, Inc.* v. *United States Food and Drug Administration, et al.*, 10 Civ. 5690 (S.D.N.Y.).

II. Background

In this section, we describe the significant rulemakings and public meetings relevant to this rulemaking and discuss our response to comments received on the 2013 Consumer Wash PR.

A. Significant Rulemakings Relevant to This Final Rule

A summary of the significant **Federal Register** publications relevant to this final rule is provided in table 1. Other publications relevant to this final rule are available at *http://www.regulations.gov* in FDA Docket No. 1975–N–0012.

TABLE 1—SIGNIFICANT RULEMAKING PUBLICATIONS RELATED TO CONSUMER ANTISEPTIC DRUG PRODUCTS [1]

FEDERAL REGISTER notice	Information in notice
1974 ANPR (September 13, 1974, 39 FR 33103).	We published an advance notice of proposed rulemaking to establish a monograph for OTC topical antimicrobial drug products, together with the recommendations of the advisory review panel (the Panel) responsible for evaluating data on the active ingredients in this drug class.
1978 Antimicrobial TFM (January 6, 1978, 43 FR 1210).	We published our tentative conclusions and proposed effectiveness testing for the drug product categories evaluated by the Panel, reflecting our evaluation of the Panel's recommendations and comments and data submitted in response to the Panel's recommendations.
1991 First Aid TFM (July 22, 1991, 56 FR 33644).	We amended the 1978 TFM to establish a separate monograph for OTC first aid antiseptic products. In the 1991 TFM, we proposed that first aid antiseptic drug products be indicated for the prevention of skin infections in minor cuts, scrapes, and burns.
1994 Healthcare Antiseptic TFM (June 17, 1994, 59 FR 31402).	We amended the 1978 TFM to establish a separate monograph for the group of products referred to as OTC topical health care antiseptic drug products. These antiseptics are generally intended for use by health care professionals. In the 1994 TFM we also recognized the need for antibacterial personal cleansing products for consumers to help prevent cross- contamination from one person to another and proposed a new antiseptic category for consumer use: Antiseptic hand wash.
2013 Consumer Antiseptic Wash TFM (December 17, 2013, 78 FR 76444).	We issued a proposed rule to amend the 1994 TFM and to establish data standards for determining whether OTC consumer antiseptic washes are GRAS/GRAE. In the 2013 Consumer Antiseptic Wash TFM, we proposed that additional safety and effectiveness data are necessary to support the safety and effectiveness of consumer antiseptic wash active ingredients.
2015 Health Care Antiseptic TFM (May 15, 2015, 80 FR 25166).	We issued a proposed rule to amend the 1994 TFM and establish data standards for determining whether OTC health care antiseptics are GRAS/GRAE. In the 2015 Health Care Antiseptic TFM, we proposed that additional data are necessary to support the safety and effectiveness of health care antiseptic active ingredients.
2016 Consumer Antiseptic Rub TFM (June 30, 2016, 81 FR 42912).	We issued a proposed rule to amend the 1994 TFM and to establish data standards for determining whether OTC consumer antiseptic rubs are GRAS/GRAE. In the 2016 Consumer Antiseptic Rub TFM, we proposed that additional safety and effectiveness data are necessary to support the safety and effectiveness of consumer antiseptic rub active ingredients.

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[1] The publications listed in table 1 can be found at FDA's "Status of OTC Rulemakings" Web site available at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm070821.htm*. The publications dated after 1993 can also be found in the FEDERAL REGISTER at *https://www.federalregister.gov*.

B. Public Meetings Relevant to This Final Rule

In addition to the **Federal Register** publications listed in table 1, there have been four meetings of the NDAC and one public feedback meeting that are relevant to the discussion of consumer antiseptic wash safety and effectiveness. These meetings are summarized in table 2.

TABLE 2—PUBLIC MEETINGS RELEVANT TO CONSUMER ANTISEPTICS

Date and type of meeting	Topic of discussion
January 1997 NDAC Meeting (Joint meeting with the Anti-Infective Drugs Advisory Committee) (January 6, 1997, 62 FR 764).	Antiseptic and antibiotic resistance in relation to an industry proposal for consumer and health care antiseptic effectiveness testing (Health Care Continuum Model) (Refs. 1 and 2).
March 2005 NDAC Meeting (February 18, 2005, 70 FR 8376)	The use of surrogate endpoints and study design issues for the in vivo testing of health care antiseptics (Ref. 3).
October 2005 NDAC Meeting (September 15, 2005, 70 FR 54560).	Benefits and risks of consumer antiseptics. NDAC expressed concern about the pervasive use of consumer antiseptic washes where there are potential risks and no demonstrable benefit. To demonstrate a clinical benefit, NDAC recommended clinical outcome studies to show that antiseptic washes are superior to nonantibacterial soap and water (Ref. 4).
November 2008 Public Feedback Meeting	Demonstration of the effectiveness of consumer antiseptics (Ref. 5).
September 2014 NDAC Meeting (July 29, 2014, 79 FR 44042).	Safety testing framework for health care antiseptic active ingredients (Ref. 6).

C. Scope of This Final Rule

This rulemaking finalizes the nonmonograph status for the 19 listed consumer antiseptic wash active ingredients (see section II.D). Requests were made that benzalkonium chloride, benzethonium chloride, and chloroxylenol be deferred from inclusion in this consumer antiseptic wash final rulemaking to allow more time for interested parties to complete the studies necessary to fill the safety and efficacy data gaps identified in the 2013 Consumer Wash PR for these ingredients. In March 2016, we agreed to defer rulemaking on these three ingredients (see Docket No. 1975–N–0012 at *http://www.regulations.gov*). Accordingly, in this final rulemaking we do not discuss whether benzalkonium chloride, benzethonium chloride, and chloroxylenol are GRAS/GRAE for use as active ingredients in consumer antiseptic washes. The monograph or new drug status of these three ingredients will be finalized either after completion and analysis of ongoing studies to address the safety and efficacy data gaps of these ingredients or at a later date if these studies are not completed.

For the 19 active ingredients included in this final rule, either no additional data were submitted since the 2013 Consumer Antiseptic Wash PR, or the data and information that were submitted were insufficient to support GRAS/GRAE findings. Therefore, these ingredients are not included in a monograph at this time. These active ingredients are not GRAS/GRAE for use in consumer antiseptic wash drug products and products containing these ingredients are new drugs for which approved new drug applications are required. Accordingly, FDA is amending part 310 (21 CFR part 310) to add the active ingredients covered by this final rule to the list in § 310.545 (21 CFR 310.545) of OTC drug products that are not GRAS/GRAE and are misbranded in the absence of an approved new drug application.

D. Eligibility for the OTC Drug Review

An OTC drug is covered by the OTC Drug Review if its conditions of use existed in the OTC drug marketplace on or before May 11, 1972 (37 FR 9464) (Ref. 7).[1] Conditions of use include, among other things, active ingredient, dosage form and strength, route of administration, and specific OTC use or indication of the product (see § 330.14(a)). To determine eligibility for the OTC Drug Review, FDA typically must have actual product labeling or a facsimile of labeling that documents the conditions of marketing of a product before May 1972 (see § 330.10(a)(2)). FDA considers a drug that is ineligible for inclusion in the OTC monograph system to be a new drug that will require FDA approval through the new drug application (NDA) process. Ineligibility for use as a consumer antiseptic rub does not affect eligibility under any other OTC drug monograph.

1. Eligible Active Ingredients

There are 19 of the antiseptic active ingredients eligible for the OTC Drug Review for use as a consumer antiseptic wash that are addressed in this final rule. These ingredients are:

- Cloflucarban
- Fluorosalan
- Hexachlorophene
- Hexylresorcinol
- Iodophors (Iodine-containing ingredients)
    - Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)
    - Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)
    - Nonylphenoxypoly (ethyleneoxy) ethanoliodine
    - Poloxamer—iodine complex
    - Povidone-iodine 5 to 10 percent
    - Undecoylium chloride iodine complex
- Methylbenzethonium chloride
- Phenol (greater than 1.5 percent)
- Phenol (less than 1.5 percent)
- Secondary amyltricresols
- Sodium oxychlorosene
- Tribromsalan
- Triclocarban
- Triclosan
- Triple dye

In the 2013 Consumer Wash PR, we describe the lack of adequate data needed for a GRAS/GRAE determination for consumer antiseptic wash active ingredients (78 FR 76444). As discussed in section II.C, rulemaking has been deferred for three of the consumer antiseptic wash active ingredients—benzalkonium chloride, benzethonium chloride, and chloroxylenol. Accordingly, any references to consumer antiseptic wash active ingredients refer only to the 19 consumer antiseptic wash active ingredients listed in this section, unless otherwise stated.

2. Ineligible Active Ingredients

In the 2013 Consumer Wash PR, we also identified certain active ingredients that were considered ineligible for evaluation under the OTC Drug Review as a consumer antiseptic wash; but, we noted that if the requested documentation for eligibility was submitted, these active ingredients could be determined to be eligible for evaluation (78 FR 76444 at 76448). The active ingredients proposed to be ineligible in the 2013 Consumer Wash PR were:

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[1] Also, note that drugs initially marketed in the United States after the OTC Drug Review began in 1972 and drugs without any U.S. marketing experience can be considered in the OTC monograph system based on submission of a time and extent application. (See § 330.14).

- Alcohol (ethyl alcohol)
- Benzalkonium cetyl phosphate
- Cetylpyridinium chloride
- Chlorhexidine gluconate
- Isopropyl alcohol
- Polyhexamethylene biguanide
- Salicylic acid
- Sodium hypochlorite
- Tea tree oil
- Combination of potassium vegetable oil solution, phosphate sequestering agent, and triethanolamine

We have not received any new information since the 2013 Consumer Wash PR demonstrating that these active ingredients are eligible for evaluation under the OTC Drug Review for use as a consumer antiseptic wash. Consequently, drug products containing these active ingredients are new drugs that will require FDA approval.

III. Comments on the Proposed Rule and FDA Response

A. Introduction

In the 2013 Consumer Wash PR, interested parties were invited to submit comments on the proposed rule by June 16, 2014. In addition, interested parties had until December 16, 2014, to submit new data or information to the docket, with 2 additional months provided to submit comments on any new data or information submitted (78 FR 76444 at 76447).

In response to the 2013 Consumer Wash PR, FDA received approximately 40 comments from drug manufacturers, trade associations, academia, testing laboratories, consumer groups, and health professionals, as well as over 1,800 comments filed by individuals. FDA also received additional data and information for certain consumer antiseptic wash active ingredients.

We describe and respond to the comments in section III.B through III.F. We have numbered each comment to help distinguish between the different comments. We have grouped similar comments together under the same number, and in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Description of General Comments and FDA Response

1. Advance Notice of Proposed Rulemaking

(Comment 1) Several comments asserted that the new efficacy testing requirements proposed in the 2013 Consumer Wash PR were unprecedented. They stated that given the significance of the proposed change to the efficacy testing requirements for consumer antiseptics and the lack of precedent for this action, FDA should withdraw the proposed rule and reissue it as an ANPR to give industry and other stakeholders an opportunity to engage with FDA on the GRAE testing requirements for the active ingredients and surrogate endpoint testing of final formulations.

(Response 1) The purpose of an ANPR is to allow the public a period of time to comment on regulations that the FDA may pursue as part of a future rulemaking. As explained in section II.A, we issued an ANPR for a monograph for OTC topical antimicrobial drug products in 1974, and a proposed rulemaking in the form of a TFM in 1978. We have amended the TFM for OTC topical antimicrobial drug products to address, for example, different categories of topical antimicrobial drug products and indications of use, as well as the need for new safety and effectiveness data based on evolving scientific developments and new information on risks associated with use of these drug products (59 FR 31402; 56 FR 33644; 78 FR 764444; 80 FR 25166; 81 FR 42912). For each amendment, we have allowed interested parties to submit comments on the proposals.

In the 2013 Consumer Wash PR, we proposed that data from clinical outcome studies (demonstrating a reduction in infections) are necessary to support a GRAE determination for consumer antiseptic wash active ingredients (78 FR 76444). We explained that, if the active ingredient in a drug product does not provide clinical benefit but potentially increases the risk associated with the drug (*e.g.,* from reproductive toxicity or carcinogenicity), then the benefit-to-risk calculation shifts, and the drug is not GRAS/GRAE. For the consumer antiseptic wash ingredients at issue here, because of new concerns about the potential risks (*e.g.,* resistance and hormonal effects), the log reduction standard (a clinical simulation standard) proposed in the 1994 TFM, which was based on an invalidated surrogate endpoint (*i.e.,* number of bacteria removed from the skin), is insufficient for establishing effectiveness of consumer antiseptic washes. Therefore, we proposed that clinical outcome studies were needed to demonstrate a direct clinical benefit.

This proposed effectiveness requirement is consistent with the NDAC's recommendations from the October 2005 NDAC meeting regarding consumer antiseptics (Ref. 4). The October 2005 NDAC concluded that the existing test methods are based on the premise that bacterial reductions translate to a reduced potential for infection, and, although bacterial reduction can be demonstrated using tests that simulate conditions of actual use, there are no corresponding clinical data to demonstrate that bacterial reductions of the required magnitude produce a corresponding reduction in infection. Accordingly, the October 2005 NDAC recommended clinical outcome studies to demonstrate the clinical benefit of consumer antiseptic wash active ingredients and their superiority compared to a nonantibacterial wash, such as soap and water. In October 2008, we also held a public feedback meeting to discuss the demonstration of effectiveness of consumer antiseptic active ingredients.

At each stage of this process, interested parties have had an opportunity to participate in these proceedings. It is not necessary now to withdraw the 2013 Consumer Wash PR and reissue it as an ANPR.

(Comment 2) Several comments argued that the 2013 Consumer Wash PR should be reissued as an ANPR because the proposed rule only requests testing on the active ingredients to demonstrate effectiveness and fails to confirm whether the Agency will impose additional surrogate efficacy requirements for a final formulation. The comments contended that the Agency's approach is inconsistent with the approach taken in the 1994 TFM and other OTC monographs.

(Response 2) The issue of whether the 2013 Consumer Wash PR should be reissued as an ANPR to include final product formulation testing does not need to be addressed in this final rule because we have determined that none of the active ingredients subject to this final rule are GRAE for use as a consumer antiseptic wash. Final formulation testing would be required for testing formulations containing active ingredients that have been determined as GRAS/GRAE.

2. Effective Date

(Comment 3) Several comments stated that FDA's timeline under the 2013 Consumer Wash PR for new data submission is unreasonable and that completing clinical outcome studies within the timeframe proposed by the Agency is unrealistic.

(Response 3) We understand that, in certain circumstances, planning, implementing, and analyzing the data generated from a clinical outcome study can be a time-consuming process that may not be completed within the period granted for submission of additional data in response to the 2013 Consumer Wash PR. Accordingly, in the 2013 Consumer Wash PR, we provided a process for seeking an extension of time to submit the required safety and/or effectiveness data if needed (78 FR 76444 at 76447). As explained in the proposed rule, we stated that we would consider all the data and information submitted to the record in conjunction with all timely and completed requests to extend the timeline to finalize the monograph status for a given ingredient (78 FR 76444 at 76447). Consideration for deferral for an ingredient was given to requests with clear statements of intent to conduct the necessary studies required to fill all the data gaps identified in the proposed rule for that ingredient. After analyzing the data and information submitted related to the requests for extensions, we determined that deferral is warranted for three consumer antiseptic wash active ingredients—benzalkonium chloride, benzethonium chloride, and chloroxylenol—to allow more time for interested parties to complete the studies necessary to fill the safety and efficacy data gaps identified for these ingredients as indicated in the 2013 Consumer Wash PR. These three ingredients are not included in this final rule and will be addressed either after completion and analysis of ongoing studies to address the safety and efficacy data gaps of these ingredients or at a later date if these studies are not completed. We decline to defer final action on the proposed rule for the 19 remaining consumer antiseptic wash active ingredients.

(Comment 4) One comment requested that the Agency finalize the monograph finding that triclosan and other antimicrobial chemicals are not GRAS/GRAE, and, in so finding, require that all consumer antiseptic wash active ingredients that are not GRAS/GRAE be removed from the market either immediately or within 6 months of the publication of the final rule.

(Response 4) As discussed in section IV of this document, the data submitted to the Agency for the non-deferred consumer antiseptic wash active ingredients is insufficient to fill all the safety and effectiveness data gaps identified in the 2013 Consumer Wash PR. Thus, we find that these consumer antiseptic wash active ingredients, including tricoslan, are not GRAS/GRAE for use in OTC consumer antiseptic wash drug products. Products containing those ingredients are therefore not eligible for inclusion in a monograph and must be removed from the market or must be approved through an NDA or an abbreviated new drug application (ANDA).

This final rule involves over 700 consumer antiseptic wash drug products, which are formulated with one or more of the 19 active ingredients discussed in this final rule. In the 2013 Consumer Wash PR, we recognized, based on the scope of products subject to this final rule, that manufacturers would need time to comply with the rule (78 FR 76444 at 76470). We therefore proposed that the final rule be effective 1 year after the publication in the **Federal Register**, finding that a period later than 1 year after publication of the final rule would neither be appropriate nor necessary (78 FR 76444 at 76470). We also believe that making the final rule effective immediately upon publication or effective 6 months after publication does not afford manufacturers the time necessary to remove from the market, or reformulate their products containing these active ingredients, given the broad scope of products that are the subject of this final rule. Thus, we decline to adopt an immediate or 6-month effective date for this rule and, instead, as discussed in section V, adopt our proposal that this final rule be effective 1 year after publication in the **Federal Register**.

3. Definition of Consumer Antiseptic Washes

(Comment 5) Several comments requested that the Agency clarify the definition of consumer antiseptic washes, stating that the definition of consumer antiseptics in the 2013 Consumer Wash PR does not include antiseptic products used in institutional settings. The commenters stated that by not including such products in the definition of consumer antiseptic washes, we put the general population at risk for increased levels of bacteria on skin, which may lead to increased infection and diseases for the general population.

(Response 5) In the 2013 Consumer Wash PR, we explained that consumer antiseptic wash drug products addressed by this rulemaking include a variety of personal care products intended to be used with water, such as antibacterial soaps, hand washes, and body washes, which may be used by consumers for personal use in the home and in certain public settings on a frequent, even daily, basis (78 FR 76444 at 76446). We also indicate that "consumer antiseptic" is a broad term and meant to include all the types of antiseptic products used on a frequent or daily basis by consumers. This is consistent with the October 2005 NDAC meeting, at which consumer antiseptics were categorized as products used by the general public, including the use of those products in institutional and public settings (Ref. 4). Therefore, we clarify that consumer antiseptic wash products are products intended for use with water by the general population in the home or public settings on a frequent or daily basis. As such, antiseptic wash products used by health care professionals or commercial food handlers or as first aid antiseptic products are not considered consumer antiseptic wash products.

4. Food Handler Antiseptics

(Comment 6) Several comments requested that FDA make a distinction between hand wash products for use by consumers and hand wash products for use by commercial food handlers. The comments explained that the food industry includes commercial enterprises involved in food processing, preparation, or handling, but does not include home preparation. In addition, they explained that the food industry provides a different environment for hand washing compared to consumer use, and as a result, a separate monograph category should be created to define standards for food handlers. An opposing comment, however, objected to FDA creating another category of antiseptics for the food industry, arguing that these antiseptics raise the same safety concerns as consumer antiseptic wash products.

The comments that advocated for a separate category for antiseptics used by the food industry stated that FDA recognized the distinction between consumer hand washes and hand washes in the food industry in the 2013 Consumer Wash PR by stating that "antiseptics for use by the food industry are not discussed further in this document" (78 FR at 76446). The comments said that, despite this statement, the absence of further language specifically addressing hand wash products for use in the food industry creates the potential that antiseptic hand wash products used in the food industry may, by default, be subject to the requirements of the 2013 Consumer Wash PR. They also requested that FDA clarify that hand wash products for use by the food industry can continue to be marketed under the current regulatory framework.

(Response 6) As stated in the 2013 Consumer Wash PR and the 2015 Health Care Antiseptic PR, we continue to classify the food handler antiseptic washes as a separate and distinct monograph category, and we clarify that such products are not part of these rulemakings on the consumer antiseptic monograph (78 FR 76444 at 76446; 80 FR 25166 at 25168). A separate category is warranted because of additional issues raised by the public health consequences of foodborne illness, differences in frequency and type of use, and contamination of the hands by grease and other oils. We plan to address OTC antiseptic products for use by the food handler industry in a separate rulemaking.[2] We plan to do a thorough evaluation of the safety and effectiveness of antiseptic active ingredients intended for this category of use. We also confirm that this final rule is not intended to affect antiseptic products indicated for use by the food industry.

C. Comments on Effectiveness and FDA Response

1. Clinical Outcome Studies

(Comment 7) Several comments challenged FDA's proposal that clinical outcome studies be conducted to demonstrate the effectiveness of the active ingredients for consumer antiseptic wash products, for the following reasons: (1) Clinical outcome studies are unjustified and not feasible; (2) the potential for antimicrobial resistance is unfounded because there has been no demonstration of a scientifically confirmed risk associated with the usage of consumer antiseptic products; (3) FDA has not properly considered the potential risks caused by lack of access to antibacterial products in consumers where specific populations of consumers may be at increased risk of infection; (4) the requirement for clinical outcome studies is far more extensive than antiseptic requirements for consumer, food, or health care antiseptics in other countries; and (5) simulation studies are a valid and feasible way to determine efficacy because they have been used since the publication of 1978 TFM, can be modified to include additional controls and surrogate endpoints that would satisfy the Agency's standards, and have been used to support approval of several NDAs.

(Response 7) In the 2013 Consumer Wash PR, we proposed that data from clinical outcome studies (demonstrating a reduction in infections) are necessary to support a GRAE determination for consumer antiseptic wash active ingredients (78 FR 76444 at 76450). We explained that new concerns about the potential risks (*e.g.*, resistance and hormonal effects) shifted the benefit-risk calculation. Therefore, the log reduction standard (a clinical simulation standard) proposed in the 1994 TFM, which was based on an invalidated surrogate endpoint (*i.e.*, number of bacteria removed from the skin), was insufficient for establishing effectiveness of consumer antiseptic washes. The requirement for clinical outcome studies is based on the fact that sufficient data to clearly demonstrate the benefit from the use of consumer antiseptic washes compared to nonantibacterial soap and water are not available. Additionally, existing data cannot demonstrate a correlation between log reductions of bacteria achieved by antiseptic hand washing in surrogate testing and reduction of infection and, as the October 2005 NDAC also concluded, the ability of consumer antiseptic wash products to decrease bacteria on the skin is insufficient for a GRAE finding if it is not supported by a direct clinical benefit (Ref. 4). Hence, in general consumer settings where soap and water are readily available the benefit of using an antiseptic wash product must be supported by clinical outcome studies. The efficacy requirements for consumer antiseptic washes differ from the efficacy requirements proposed for consumer antiseptic rub products because the wash products are intended to be used when soap and water are not available (81 FR 42912) (2016 Consumer Rub PR). In addition, the consumer antiseptic wash efficacy requirements differ from the efficacy requirements for health care antiseptics used in a hospital setting, where study design limitations and ethical concerns prevent the use of clinical outcome studies (80 FR 25166 at 25175 to 25176).

Moreover, as explained in the 2013 Consumer Wash PR, FDA's OTC regulations (§ 330.10(a)(4)(ii)) define the standards for establishing an OTC active ingredient as GRAE. These regulations require the efficacy of active ingredients for OTC drug products be demonstrated by controlled clinical trials (§§ 330.10(a)(4)(ii) and 314.126(b) (21 CFR 314.126(b)), unless this requirement is waived as provided in § 330.10(a)(4)(ii). These studies must be well controlled and able to distinguish the effect of a drug from other influences, such as a spontaneous change in the course of the disease, placebo effect, or biased observation (§ 314.126(a)).

The requirement for controlled clinical trials also is consistent with the recommendations of the October 2005 NDAC that clinical outcome studies be used to demonstrate the clinical benefit of consumer antiseptic wash products and their superiority compared to a nonantibacterial wash, such as soap and water (Ref. 4). Although two clinical outcome studies we identified in the 2013 Consumer Wash PR did not demonstrate a benefit from the use of the tested antiseptic active ingredient, these studies were randomized, blinded, and placebo-controlled, and demonstrate that such clinical outcome studies are feasible. For these reasons, FDA's requirement that clinical outcome studies be conducted to demonstrate the effectiveness of the active ingredients for consumer antiseptic wash products is warranted and reasonable.

(Comment 8) One comment also argued that FDA's requirement for clinical outcome studies based on its concern about the potential for increased antimicrobial resistance and endocrine disruption because of use of consumer antiseptic wash active ingredients is unfounded. The comment asserted that the requirement of clinical outcome studies is not supported by any demonstration of a confirmed risk associated with the use of consumer antiseptic products.

(Response 8) We agree that the development of resistant mechanisms in natural settings is not sufficiently studied. However, as discussed in more detail in section III.D.2, the concerns regarding the extended use of antiseptics, its potential consequences on the systemic exposure, and its potential consequences on the development of bacterial resistance, must be assessed. A GRAS/GRAE determination for an active ingredient for a particular intended use requires a benefit-to-risk assessment—in this case, the risk posed by use of a consumer antiseptic wash drug product must be balanced by a demonstration that the product is statistically significant (p-value <0.05) in reducing infections compared to washing with nonantibacterial soap and water, which refers to a soap formulation, solid or liquid, that does not contain any antimicrobial ingredient.

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[2] The Personal Care Products Council and American Cleaning Institute submitted a citizen petition in this rulemaking requesting FDA action on issues related to food handler antiseptic wash products. This citizen petition and other issues related to food handler products will be addressed in future documents.

(Comment 9) Commenters also contend the Agency has not considered the potential risks of an increase in infections among consumers by their not having access to antibacterial product formulations and commenters included publications in support of their position.

(Response 9) Although the submitted publications demonstrate some increase of infection in consumer settings, they do not address the effectiveness of consumer antiseptic wash products in the prevention or reduction of infections. The cited studies underscore the urgency of scientifically demonstrating the contribution of consumer antiseptics in lowering the infection rates in consumer settings. Although we acknowledge that there may be populations with increased vulnerability to bacterial infection, such as the elderly and persons with suppressed immune systems, the data to support the benefit of the use of consumer antiseptic wash products over that of nonantibacterial soap and water in these populations is still lacking.

(Comment 10) Several comments stated that the clinical outcome requirements proposed in the 2013 Consumer Wash PR are more extensive and demanding than requirements for establishing GRAE for active ingredients in other OTC monographs, and more demanding than what is required for antiseptics that are approved for use in other countries.

(Response 10) Although the requirement for clinical outcome studies for consumer antiseptic wash active ingredients may be a more stringent requirement than is used by some other countries, FDA's proposed effectiveness requirement is supported by FDA's regulations, the recommendations of the October 2005 NDAC, as well as by available data and publications studying the clinical outcome of antiseptics, all of which support the requirement of clinical outcome studies (Refs. 8 and 9). Moreover, the existence of published studies demonstrates that clinical outcome studies are feasible. For the reasons explained in this section, clinical outcome studies are necessary to assure that the potential risk from use of consumer antiseptic wash products is balanced by a demonstrated clinical benefit.

(Comment 11) Several comments argued that clinical simulation studies are a valid way to demonstrate efficacy and that the log reduction of bacteria on skin proposed to demonstrate efficacy since the 1978 TFM, has been used to support the approval of several NDAs. The comments also proposed that clinical simulation studies can be modified to include additional controls and neutralizers to satisfy the Agency's requirements. The comments stated that neutralization solutions are already included in the American Society for Testing and Materials (ASTM)[3] E1174 "Standard Test method for Evaluation of the Effectiveness of Health Care Personnel Hand Wash Formulations," and a vehicle control and an active control such as Hibiclens 4 percent could also be included in clinical simulation studies.

(Response 11) We agree that clinical simulation studies and surrogate endpoints have been used since the publication of the 1978 TFM (43 FR 1210) and continued to be a requirement for demonstrating effectiveness in the 1994 TFM (59 FR 31402). As addressed in the 2015 Health Care Antiseptic PR (80 FR 25166), we will continue to evaluate the effectiveness of health care antiseptic products based on both in vitro testing and clinical simulation studies. However, the ethical concerns and challenges of designing clinical trials in the hospital setting do not apply to the consumer antiseptic wash setting, where washing with soap and water is a readily available alternative for consumers, and clinical trials to demonstrate clinical superiority are ethical and feasible.

With respect to approved marketing applications, we note that the Agency has not approved any applications for consumer antiseptic wash products since the publication of the 1994 TFM. The approved NDA products for which evaluation of efficacy is based on in vitro testing results and clinical simulation studies have been for antiseptic products used in the health care setting.

Moreover, although the addition of vehicle and active controls, as well as the inclusion of neutralization solutions in the test method, may increase the accuracy of the testing itself, it does not meet the requirement of establishing a direct connection between the use of consumer antiseptic wash active ingredients and infection reduction in a general consumer setting. A surrogate study, with or without additional controls, is founded on the premise that reduction of bacteria on skin because of use of a consumer antiseptic active ingredient (or product) will result in reduction of infections, but it is not a direct proof of reduced infections. While we continue to propose the use of surrogate endpoints as a demonstration of effectiveness for health care antiseptics and consumer antiseptic rubs, the reasons for those different requirements, such as the challenges of conducting such studies in the health care setting, and the fact that consumer rubs, which are intended for use when soap and water is unavailable, do not apply to consumer antiseptic wash products used in general consumer settings. In addition, the infection risk in healthcare settings is greater than in consumer settings, and as such, a clinical outcome study for healthcare antiseptics raises ethical questions regarding the use of non-antimicrobial vehicle in patients. Studying the effectiveness of consumer wash antiseptics via clinical outcome studies in consumer settings is not unethical and, as previously shown, it is feasible (Refs. 8 and 9).

As stated in the 2013 Consumer Wash PR, we have evaluated all clinical simulation studies that were submitted to the OTC Drug Review for evidence of antiseptic consumer wash active ingredient effectiveness demonstrated under the log reduction criteria (78 FR 76444 at 76451). We also evaluated the publications referenced in the comments submitted in response to the 2013 Consumer Wash PR. The studies described in the referenced publications lack the appropriate controls of a clinical outcome study, so we cannot, without additional evidence, attribute the reduction of infection rates to the use of antiseptic consumer wash active ingredients (Refs. 10 and 11). In sum, the studies we have evaluated are not adequately controlled to support an accurate assessment of the effectiveness of consumer antiseptic wash active ingredients.

A demonstration of the effectiveness of the active ingredients used in consumer antiseptic wash products should result from robust, properly designed, randomized studies with adequate numbers of subjects and clearly defined endpoints and analysis, using reduction in infection rates rather than reduction in pathogen counts. For the reasons discussed in this section and in the 2013 Consumer Wash PR, adequate clinical outcome studies that identify the conditions of use on which an antiseptic active ingredient can demonstrate a reduction in the number of infections, are required to demonstrate the GRAE status of consumer antiseptic wash active ingredients.

2. Testing of the Active Ingredient

(Comment 12) Several comments argued that the testing of the active ingredients rather than testing of final formulation products is unnecessary and not feasible because the delivery of the active ingredient is heavily dependent on its vehicle and testing of the active ingredient alone is not possible. One comment stated that although several consumer antiseptic wash products may contain the same active ingredient, they can also contain different product formulations that account for the effective delivery of the active ingredient, and, thus, test results of one specific wash product may not represent the effectiveness of a variety of consumer antiseptic wash products formulated with the same active ingredient.

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[3] General information about ASTM can be found at *https://www.astm.org/*.

(Response 12) The controlled clinical trials required by FDA's regulations are intended to demonstrate that the pharmacological effect of the drug when used under adequate directions for use will provide clinically significant relief of the type claimed (§§ 330.10(a)(4)(ii) and 314.126(b); 78 FR 76444 at 76450)), *i.e.* efficacy for the stated indication. GRAE determinations are made based on the active ingredient, not the product. We understand that testing the effectiveness of only the active ingredient using clinical outcome studies may not be feasible because the consumer uses the product in its final formulation form and not necessarily in the form of the isolated active ingredient. We agree that a variety of aspects of a final product formulation such as its pH, surfactancy, solubility, as well as the product's stability, depend on the formulation of the vehicle and can have an impact on the delivery of the active ingredient, as well as its antibacterial activity. We agree that test results of one specific wash product may not represent the effectiveness of a variety of consumer antiseptic wash products formulated with the same active ingredient. However, the proposal for conducting adequate and well-controlled clinical outcome studies to demonstrate that the active ingredient of a consumer antiseptic wash product is GRAE was not intended to be a study conducted only on the active ingredient, but rather a study designed to determine the contribution of the active ingredient to the effectiveness of the product. To determine that the active ingredient is GRAE, the clinical outcome studies should include at least two arms: The final formulation of the product and the vehicle. The effectiveness of the active ingredient, and hence its contribution in the reduction of infections, will be determined by comparing the infection rate of the active ingredient plus its vehicle to the infection rate of the vehicle in a consumer population. In the 2013 Consumer Wash PR, the referenced clinical outcome studies (Refs. 8 and 9) are two-arm studies where the effect of the antiseptic product in reduction of infections in a population is compared to a non-antibacterial product. It is in the presence of these controls (*i.e.,* the vehicle or a non-antibacterial product) that the contribution of the active ingredient contained in a consumer wash antiseptic product can be determined. We note that if an ingredient is so highly formulation dependent that the results of the efficacy testing cannot be extrapolated to demonstrate the active ingredient's effectiveness, products containing such an ingredient may require an NDA.

3. In Vitro Testing/Time-Kill Assays

(Comment 13) Several comments urged FDA to revise its proposed in vitro test methods for consumer wash antiseptic active ingredients. They stated that for demonstrating antibacterial activity of active ingredients, it is more relevant to perform a minimal inhibitory concentration and minimal lethal concentration (MIC/MLC) test to determine the potency and spectrum of the antibacterial activity of the proposed active ingredient before it is included in an antibacterial product formulation. Several comments also recommended that FDA not establish specific performance criteria for MIC/MLC testing of the active ingredients because the ingredients have not yet been formulated.

(Response 13) In addition to the clinical outcome studies FDA proposed in the 2013 Consumer Wash PR, FDA proposed an in vitro study consisting of a modified time-kill assay conducted on selected reference organisms and their respective clinical isolates, which are representative of bacterial strains most commonly encountered in general consumer settings (78 FR 76444 at 76452 to 76453). The purpose of the in vitro study is to characterize the antimicrobial activity of the active ingredients used in consumer antiseptic wash products.

As explained in the 2013 Consumer Wash PR, the requirement for clinical outcome studies lessens the need for extensive in vitro studies, given that the primary support for a GRAE determination is the clinical outcome study. MIC/MLC tests assess the minimal concentration of the active ingredient needed to cause inhibition of growth and/or lethality to bacteria after a 24-hour exposure to the active ingredient. However, the exposure time of consumer wash active ingredients, based on the indications of use for antiseptic wash products, is much shorter—several minutes maximum. Thus, information on the ability of the antiseptic wash active ingredient to inhibit or eliminate bacterial growth after the prolonged exposure times used in the MIC/MLC testing is not relevant to the actual use of the consumer antiseptic wash product.

The time-kill assay, on the other hand, is designed to test shorter exposure times against the microorganisms selected for testing with the test material, and as such, it provides more relevant information on how quickly the tested active ingredient eliminates the tested microorganisms. The time-kill assay also includes strains and clinical isolates of organisms most commonly found in consumer settings and provides relevant information on the kinetics of the antimicrobial activity of active ingredients with regard to the bactericidal activity of active ingredients used in consumer antiseptic wash products.

Given that we are not requiring MIC/MLC tests to be performed, we do not address whether specific performance criteria should or should not be established for MIC/MLC testing of the active ingredients.

(Comment 14) Several comments also contended that the time-kill assay should be used for characterization of final product formulation, rather than for evaluation of the effectiveness of the active ingredient, given that many characteristics of the formulation, such as its stability, solubility, and pH, have a significant influence on the performance outcome of the antiseptic product. They urged FDA to adopt ASTM E2783, "Standard Test Method for Assessment of Antimicrobial Activity for Water Miscible Compounds Using a Time-Kill Procedure," as the standard for conducting the time-kill assay. They also argued that the performance criteria for the time-kill assay proposed in the 2013 Consumer Wash PR are more demanding than the performance abilities of approved health care antiseptic products.

(Response 14) Testing requirements for the final product formulations are not addressed in this final rule because none of the active ingredients that are the subject of this final rule are considered GRAE for use in consumer antiseptic wash products, given the lack of sufficient effectiveness data for these ingredients. The testing requirements for final formulations of products containing the three deferred active ingredients will be addressed after a decision is made regarding the monograph status of those ingredients.

In addition, for purposes of the three deferred active ingredients, we have reviewed the ASTM E2783–11 and do not disagree with the use of this method for the deferred active ingredients to help establish GRAE status for a consumer antiseptic wash product with a bacterial indication, as long as all the bacterial strains and the respective clinical isolates proposed in the 2013 Consumer Wash PR are included in the test.

With regard to the comment that the performance criteria of the time-kill assay are more demanding than the performance abilities of approved health care antiseptic products, the proposed 99.9 percent elimination of bacteria describes the concentration and the time of contact at which the active ingredient would be considered bactericidal. This criterion is based on the performance of alcohol formulations (61 percent to 85 percent) and on the expectation that an effective consumer antiseptic product will demonstrate a comparable bactericidal activity. The 2013 Consumer Wash PR did not propose that a 99.9 percent performance criterion would have to be achieved on all the proposed reference strains and clinical isolates to make a GRAE determination for the active ingredient.

In summary, the clinical results necessary to support a GRAE finding for any of the consumer antiseptic wash active ingredients addressed in this final rule have not been demonstrated. The effectiveness of each of the three consumer wash active ingredients deferred from this rulemaking will be evaluated on a case-by-case basis in the future.

4. Melon Ball Model To Support a GRAE Determination

In the 2013 Consumer Wash PR, we evaluated a study submitted to the OTC Drug Review involving a testing protocol referred to as the Melon Ball Disease Transmission (MBDT) model (78 FR 76444 at 76451 to 76452). The MBDT model attempts to link the efficacy of washing with antibacterial consumer wash to infection reduction by correlating the reduction of bacterial transfer to a food item following the use of a consumer antiseptic hand wash to a reduction of infection. In the 2013 Consumer Wash PR, FDA raised several concerns regarding the validity of the MBDT model. We found the MBDT model deficient and inadequate to link reduction of bacteria to a reduction in infection incidences (78 FR 76444 at 76451). Therefore, we concluded, the results of the MBDT study did not demonstrate the effectiveness of the consumer antiseptic hand wash used in the study.

(Comment 15) Several comments disagreed with the Agency's concerns and supported the use of the MBDT model for establishing a GRAE classification for relevant active ingredients, as well as supported optional final formulation testing that is intended to correlate clinical simulation study results with clinical outcome. Published data and recent studies were included in the comments submitted in response to the 2013 Consumer Wash PR to address the validity of the MBDT model and two other models used along with the MBDT model: (1) The Palmar hand-contamination method—the model of bacterial hand contamination and (2) a computational simulation model known as the Quantitative Microbial Risk Assessment (QMRA) model.

(Response 15) We reviewed and evaluated the submitted materials, including the studies previously addressed in the 2013 Consumer Wash PR. The studies show a reduction of bacteria on skin, as well as reduced bacterial transfer from hands to objects or food items because of use of consumer antiseptic wash products. In the Schaffner et al. study, statistical analysis and the QMRA model were used, in addition to the previously reported MBDT model, in an effort to establish a quantitative link between the effectiveness of antiseptic products and the reduced potential for disease such as *Shigellosis* and other low-dose enteric pathogens (Ref. 12).

After evaluation, however, we find that the submitted data, which include the Palmar method and QMRA model, do not address the deficiencies of the MBDT model previously analyzed in the 2013 Consumer Wash PR for the following reasons:

- The Palmar method is not reflective of the intended use of consumer antiseptic wash products and does not take into consideration the bacteria residing under the fingernails, which is an important reservoir for bacteria. Sufficient data to compare the Palmar method to the full-hand contamination method currently used are not provided.
- The limitations of the dose-response model generated from *S. flexneri* dose-response studies, including the small number of subjects, variability in the dose-response data, and lack of uniformity on criteria used for the definition of illness, remains the same as previously addressed in the 2013 Consumer Wash PR (78 FR 76444 at 76451).
- Although melon is a readily found food item, it cannot be used as a standardized tool for bacterial transfer. There are other factors besides the size of the melon balls, such as the melon's ripeness and surface texture, which may introduce variability to bacterial transfer. Also, bacterial transfer may be affected by the amount of fat/grease contained in a food item. These issues cannot be addressed by using the melon ball as a standardized object to study bacterial transfer (Ref. 13). The comments provided no useful data to assess the effects of these variables on the absolute counts of bacteria transferred from hands to food items and the overall study outcome.

Overall, the MBDT model, including the QMRA analysis, cannot be used as a standardized method to validate the effectiveness of consumer antiseptic wash active ingredients. Such a model assesses bacterial transfer as a surrogate for disease and is not capable of showing the direct clinical benefit of an antiseptic active ingredient or an antiseptic product for the general consumer population. Instead, it measures the transfer of bacteria from contaminated hands to melon balls, a measurement that is then used in a risk assessment model to provide a hypothetical infection reduction estimate based on infection data generated from *S. flexneri* dose-response studies with limited data. The proposed MBDT model reflects only one facet of the multiple uses of consumer antiseptic wash products. Consumers can be exposed to pathogenic organisms not only through food preparation activities, but also through contact with a variety of fomites in the domestic setting. Furthermore, the MBDT model does not address the scenario where a consumer would transfer the disease from their contaminated hands to other parts of their bodies (self-inoculate).

Although the QMRA analysis may be useful for exploratory analysis for risk assessment and management, it is not used for demonstrating the efficacy of drugs for approval. The comment provided references to show that QMRA analyses have been adopted by many agencies, including FDA. Our literature search confirms that QMRA analyses are used to estimate the impact of food safety policies (Ref. 14), or to predict the probability of adverse effects in vaccination (Ref. 15). However, we did not find any evidence of QMRA analysis employed as direct proof in determining the efficacy of a drug product or an active ingredient.

The MBDT model fails to prove that reduction of the pathogen counts on hands will translate into a clinically meaningful benefit, and as such, the MBDT model cannot be a substitute for adequate clinical outcome studies that identify conditions of use under which an antiseptic wash active ingredient is capable of reducing the number of infections. The data demonstrating the effectiveness of the active ingredients used in consumer antiseptic wash products should result from robust, properly designed, randomized studies with adequate numbers of subjects and clearly defined endpoints and analysis, assessing reduction in infection rates rather than reduction in pathogen counts.

5. American Society for Testing and Materials Standard Methods

(Comment 16) Several comments addressed the test methods for demonstration of effectiveness for final product formulations and proposed that the Agency recognize several ASTM test methods for determination of effectiveness for final product formulations, including the ASTM E1174 "Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Hand Wash Formulations," the ASTM E2784 "Standard Test Method for Evaluation of the Effectiveness of Hand Wash Formulations Using the Paper Towel (Palmar) Method of Hand Contamination," the ASTM E1874 "Standard Test Methods for Recovery of Microorganisms From Skin Using the Cup Scrub Technique," and the ASTM E2783 method "Standard Test Method for Assessment of Antimicrobial Activity for Water Miscible Compounds Using a Time-Kill Procedure."

(Response 16) As discussed in section IV, none of the active ingredients subject to this final rule have been found to be GRAE for use in a consumer antiseptic wash product. We will evaluate the GRAS/GRAE status of the three deferred active ingredients either upon completion and analysis of all safety and effectiveness studies required for these ingredients or at a later date if these studies are not completed (78 FR 76444 at 76458). For these reasons, it is premature to discuss final product formulation testing requirements before a decision is made on the adequacy of data to provide to support monograph status of the three deferred active ingredients.

We note, however, that the suggestion to accept the ASTM test methods used in clinical simulation studies for final product formulation testing is based on the assumption that for the consumer antiseptic wash active ingredients for which clinical outcome studies will demonstrate effectiveness, only antibacterial claims would be supported. The guidelines for clinical outcome study design provided by the Agency with regard to the three deferred consumer antiseptic wash active ingredients allow for demonstration of reduction of infections of either bacterial or viral origin. If the clinical outcome studies demonstrate that these active ingredients can reduce infections of origin other than bacterial (*i.e.* viruses), additional testing to further characterize the activity of these ingredients must be determined. Therefore, testing requirements for final product formulation cannot be finalized before we have made a determination that a deferred active ingredient is GRAE. Depending on the indication(s) supported by clinical outcome studies for an active ingredient, additional final product formulation testing, other than the ASTM methods suggested, may be required.

D. Comments on Safety and FDA Response

1. Additional Safety Testing Requirements

(Comment 17) One comment stated that before proposing new safety testing, FDA must consider the actual risks. The comment argued that if current product exposures do not present risk based on the existing data, new data should not be required. The comment further recommended that existing data should be reviewed in relation to increased risk rather than increased analytic sensitivity and that if FDA finds that there is no demonstration of risk, FDA should conclude that the active ingredients and formulations are safe.

(Response 17) We decline to withdraw our requirement in the 2013 Consumer Wash PR for the additional safety data that we determined is necessary to support a GRAS classification for the consumer antiseptic wash active ingredients. As explained in the 2013 Consumer Wash PR, several important scientific developments that affect the safety evaluation of the consumer antiseptic wash active ingredients have occurred since FDA's 1994 evaluation. New data and information on the antiseptic wash active ingredients raise concerns regarding potential risks from systemic absorption and long-term exposure, as well as development of bacterial resistance related to use of consumer antiseptic washes (78 FR 76444 at 76445). The data required by the 2013 Consumer Wash PR is necessary for FDA to conduct an adequate safety evaluation. The comments do not provide sufficient data to support a determination that these consumers antiseptic wash active ingredients can be classified as GRAS.

2. Resistance

(Comment 18) Numerous comments relating to the issue of bacterial resistance were submitted in response to the 2013 Consumer Wash PR. Some comments argued that the pervasive use of consumer antiseptics poses an unacceptable risk for the development of resistance and that these products should be removed from the market. Other comments disagreed and criticized the data on which they believe FDA has based its concerns.

Specifically, several comments dismissed the in vitro data cited by FDA in the 2013 Consumer Wash PR as not reflecting real-life conditions. The comments recommended that the most useful assessment of the risk of biocide resistance and cross-resistance to antibiotics are in-situ studies, studies of clinical and environmental strains, or biomonitoring studies. Some comments asserted that studies of this type have reinforced the evidence that resistance and cross-resistance associated with antiseptics is a laboratory phenomenon observed only when tests are conducted under unrealistic conditions. Another comment cited the conclusions of an International Conference on Antimicrobial Research held in 2012 on a possible connection between biocide (antiseptic or disinfectant) resistance and antibiotic resistance to support the point that there is no correlation between antiseptic use and antibiotic resistance (Ref. 16).

(Response 18) Laboratory studies have identified and characterized bacterial resistance mechanisms that confer a reduced susceptibility to antiseptics and, in some cases, clinically relevant antibiotics (Refs. 17 through 27). Bacteria expressing these resistance mechanisms with a decreased susceptibility to antiseptics have been isolated from a variety of natural settings (Refs. 28 through 30). These studies found that the prevalence of antiseptic tolerant subpopulations in the natural microbial populations studied is currently low. Morrissey et al. concluded, however, that their study findings could not rule out the existence of other resistant isolates that could be found if more isolates were analyzed.

In general, studies have not clearly demonstrated an impact of antiseptic bacterial resistance mechanisms in the natural setting. However, the available studies have limitations. As FDA noted in the 2013 Consumer Wash PR, studies in a natural setting that it evaluated were limited by the small numbers and types of organisms, the brief time periods, and the locations examined; and more importantly, none of these studies address the level of exposure to the antiseptic active ingredient (Refs. 30 through 33) (78 FR 76444 at 76454). These limitations were also found in the studies cited by the comments (Refs. 35 through 37). There was, however, one study that found a difference in the antiseptic and antibiotic susceptibilities of some of the bacteria evaluated (Ref. 38).

Carson et al. assessed the effect of antibacterial product use (cleaning products containing quaternary ammonium compounds including benzalkonium chloride and hand soap containing 0.2 percent triclosan) in the home environment on susceptibility to benzalkonium chloride, triclosan, and antibiotics. Data were collected as part of a longitudinal double-blind, randomized clinical trial that compared the susceptibilities of bacteria isolated from antibacterial user and nonuser households at baseline and after 1 year. The MICs of 645 isolates were evaluated. The study found that after 1 year of assigned product usage, bacterial isolates with high benzalkonium chloride MICs were more likely to have high triclosan MICs and be resistant to one or more antibiotics.

Other data on a possible correlation between antiseptic and antibiotic resistance are conflicting. Copitch et al. found that the majority of isolates with decreased resistance to triclosan were also resistant to multiple antibiotics in their series of 428 isolates screened for decreased susceptibility to triclosan and a panel of antibiotics (Ref. 29). Conversely, Skovgaard et al. found no significant association between antibiotic resistance and triclosan tolerance when they compared the susceptibilities of current isolates of *Staphylococcus epidermidis* with isolates collected in the 1960s before introduction of triclosan to the market in Denmark (Ref. 30). An analysis of 1,600 isolates of *Staphlococcus aureus* has shown a moderate correlation between susceptibility to benzalkonium chloride and some classes of antibiotics (*e.g.*, quinolones, beta-lactams, and macrolides), but not for triclosan (Ref. 39).

In conclusion, bacteria expressing resistance mechanisms with a decreased susceptibility to antiseptics and some antibiotics have been isolated from a variety of natural settings (Refs. 28 and 29). Although the prevalence of antiseptic tolerant subpopulations in natural microbial populations is currently low, continued overuse of antiseptic active ingredients has the potential to select for resistant microorganisms.

Adequate data do not currently exist to determine whether the development of bacterial antiseptic resistance could also select for antibiotic resistant bacteria or how significant this selective pressure would be relative to the overuse of antibiotics, an important driver for antibiotic resistance. Moreover, the possible correlation between antiseptic and antibiotic resistance is not the only concern. Reduced antiseptic susceptibility may allow the persistence of organisms in the presence of low-level residues and contribute to the survival of antibiotic resistant organisms. Data are not currently available to assess the magnitude of this risk.

(Comment 19) Other comments disagreed that the development of resistance to a particular ingredient has been demonstrated. The comments also disagreed on the type of data needed to assess the risk of the development of resistance. One comment disagreed with the proposed testing described in the 2013 Consumer Wash PR, arguing that there are no standard laboratory methods for evaluating the development of antimicrobial resistance. With regard to the recommendation for mechanism studies, some comments asserted that it is unlikely that this kind of information can be developed for all active ingredients, particularly given that the mechanism(s) of action may be concentration dependent and combination/formulation effects may be highly relevant. The comments also believed that data characterizing the potential for transferring a resistance determinant to other bacteria is an unrealistic requirement for a GRAS determination.

Conversely, one comment recommended that antimicrobial resistance be addressed first through in vitro MIC determinations. If an organism is shown to develop resistance rapidly, then the comment recommended that FDA should consider this negative information in its evaluation. The comment believed that this test of the potential for the development of resistance is important because consumer compliance with recommended use of consumer antiseptic wash products is variable and products that result in rapid antimicrobial resistance would pose a public health risk.

(Response 19) In the 2013 Consumer Wash PR, we proposed a tiered approach as an efficient means of developing data to address this issue. Laboratory studies were proposed as a feasible first step in evaluating the impact of exposure to nonlethal amounts of antiseptic active ingredients on antiseptic and antibiotic bacterial susceptibilities. We noted that only limited data exist on the effects of antiseptic exposure on the bacteria that are predominant in the oral cavity, gut, skin flora, and the environment, and that these organisms represent pools of resistance determinants that are potentially transferable to human pathogens (78 FR 76444 at 76457). Thus, we proposed broader laboratory testing of consumer antiseptic active ingredients that would more clearly define the scope of the impact of antiseptic active ingredients on the development of antibiotic resistance and may enable identification of those antiseptic active ingredients for which the development of resistance is not a concern. We are aware that there are no standard protocols for these studies. However, there are numerous publications in the literature of studies of this type that could provide guidance on the study design (Refs. 40 through 44).

For antiseptic active ingredients for which an effect on antiseptic and antibiotic susceptibilities is demonstrated, we proposed that additional data would be necessary to help assess the likelihood that changes in susceptibility observed in the preliminary studies would occur in the consumer setting. Several different types of data were recommended to assess whether or not ingredients with positive laboratory findings pose a public health risk, and the type of data needed would depend on what is already known about the antiseptic active ingredient's mechanism of action and persistence in the environment. We stated that we did not anticipate that it would be necessary to obtain data from multiple types of studies for each active ingredient to adequately assess its potential to affect resistance. Thus, the types of studies that would be acceptable to help address this issue are not limited to those described in the 2013 Consumer Wash PR (78 FR 76444 at 76457).

(Comment 20) One comment noted that the recommendations in the proposed rule pertaining to the type of data that could be used did not consider the safety of usage of antiseptics for another sensitive population: The immunocompromised. The comment stated that this growing population may be at greater risk of developing bacterial resistance from repeated usage of antiseptics, and the comment noted the dangers that result from associated infections that are unresponsive to traditional antibiotics. The comment submitted no data to support its assertion, but asserted that there is a need for research to clarify whether the bacterial composition of immunocompromised individuals is adequately represented by the bacteria identified for testing in the proposed rule. The comment also suggested that there may be an additional need to perform surveillance of the effects seen in the immunocompromised after the use of consumer antiseptics for increased risk of bacterial resistance, because this has been demonstrated in clinical settings. Another comment recommended that FDA require that manufacturers establish and maintain active surveillance of this issue and require that this information be submitted to FDA every year.

(Response 20) We acknowledge that there are segments of the general population that may be more at risk from antiseptic/antibiotic cross-resistance and that further research is needed to address this facet of this issue. However, because no monograph is being established for the consumer antiseptic wash active ingredients in this final rule, the requests for an FDA requirement for active surveillance of this issue do not apply for purposes of this final rule.

3. Alternatives to Animal Studies

(Comment 21) One comment requested that FDA provide guidance on how to reduce the use of animals in testing done to assess the safety of consumer antiseptic washes. The comment recommended that FDA require manufacturers to conduct efficacy testing in humans before safety testing in animals and to share the data resulting from any animal testing they conduct. The comment also recommended that FDA accept data from non-animal safety tests.

In addition, the comment recommended that FDA reduce the number of rodent cancer bioassays required, by allowing for the extrapolation of data from the dermal route of administration to the oral route, and from the oral route to the dermal route. The comment requested that FDA consider whether physiologically based toxicokinetic modeling (PBTK), along with certain non-animal in vivo and in vitro absorption, distribution, metabolism, and excretion (ADME) data, could support route-to-route extrapolation. The comment further recommended that FDA adopt in vitro testing strategies to replace testing using animal models. Lastly, the comment stated that FDA should require manufacturers to share the data resulting from any animal testing they conduct.

(Response 21) The required number of rodent cancer bioassay studies have in some cases been reduced for drug products; for instance, a waiver of dermal carcinogenicity may be considered for a substance used previously by another route if a chronic dermal study in an appropriate non-rodent species shows no potential neoplastic effects and there are no other causes for concern, such as absence of a positive genotoxicity signal and absence of association of exposure to the drug with a positive tumor signal in systemic carcinogenicity data (Refs. 45 and 46). However, at this point, the Agency has not adopted a policy regarding the use of route to route extrapolation method using alternatives to animal testing such as in vitro data, ADME and PBTK tools.

We understand that animal use in tests for the efficacy and safety of human and animal products has been and continues to be a concern. We encourage sponsors to consult with us on non-animal testing methods they believe may be suitable, adequate, validated, and feasible. We are willing to consider if alternative methods could be assessed for equivalency to an animal test method.

However, there are still many areas where animal testing is considered necessary and non-animal testing is not yet a fully available option. FDA continues to support efforts to reduce animal testing, particularly whenever new alternative methods for safety evaluation have been validated and accepted by International Council on Harmonization (ICH) regulatory authorities, but these efforts have not yet resulted in the development of alternative testing that eliminate animal testing altogether. We will not be discussing further in this final rule the specific issues raised in the comments on animal testing because these issues are outside the scope of this rulemaking.

With respect to the recommendation that FDA require manufacturers to share the data resulting from any animal testing they conduct, FDA regulations require that data and information relevant to the monograph and a GRAS/GRAE determination be submitted to the docket for that monograph and made publicly available (§ 330.10(a)(2)). Accordingly, any such animal testing data should be publicly available and can be obtained from the docket for this rulemaking. We also note that although there is a process for submitting confidential information, the OTC drug monograph process is generally a public process. The Agency considers either non-confidential material that is submitted to the docket or information that is publicly available when making its evaluation of whether a given ingredient is GRAS/GRAE.

E. Comments on Active Ingredients and FDA Response

1. Ethanol

(Comment 22) A comment was submitted to this docket regarding the GRAS status of ethanol.

(Response 22) This active ingredient is not marketed as a consumer antiseptic wash product, and, therefore is not addressed. We will address this comment, and any other comments regarding the GRAS status of ethanol, to the extent that it applies to indications reviewed in the 2015 Health Care Antiseptic PR and the 2016 Consumer Rub PR.

2. Cetylpyridinium Chloride

(Comment 23) As noted in the 2013 Consumer Wash PR, subsequent to the 1994 TFM we received requests that certain active ingredients be added to the antibacterial monograph (78 FR 764444 at 76448). One of these submissions included a citizen petition that requested that we allow the use of cetylpyridinium chloride as an antibacterial active ingredient for household liquid soap (Ref. 47).

(Response 23) In the 2013 Consumer Wash PR, we identified certain active ingredients, including cetylpyridinium chloride that we considered ineligible for evaluation under the OTC Drug Review as a consumer antiseptic wash. We noted that if the requested documentation for eligibility was submitted, these active ingredients, including cetylpyridinium chloride, could be determined to be eligible for evaluation (78 FR 76444 at 76448). Neither the citizen petition, nor other submissions we have received in this rulemaking, include documentation demonstrating the eligibility of cetylpryridinium chloride for evaluation under the OTC Drug Review for use as a consumer antiseptic wash. Consequently, this citizen petition is denied and as indicated in section II.D, we consider consumer antiseptic wash products containing cetylpyridinium chloride to be new drugs that require FDA approval through the NDA process.

3. Hexylrescorinol

In the 2013 Consumer Wash PR, FDA proposed to classify hexylresorcinol as Category III for both safety and efficacy (78 FR 76444 at 76458). FDA determined that the administrative record for the safety of hexylresorcinol was incomplete with respect to the following:

- Human pharmacokinetic studies under the maximal use conditions when applied topically, including documentation of validation of the methods used to measure hexylresorcinol and its metabolites
- Animal pharmacokinetic studies on ADME
- Data to help define the effect of formulation on dermal absorption
- Dermal carcinogenicity
- Developmental and reproductive toxicity (DART) data
- Potential hormonal effects
- Data from laboratory studies that assess the potential for the development of resistance to hexylresorcinol and cross-resistance to antibiotics in the types of organisms listed in section VII.C.3 of the 2013 Consumer Wash PR (78 FR 76444 at 76457)

(Comment 24) One comment referenced a 13-week oral toxicology study from the National Toxicology Program (NTP) conducted in rats, in which there were reports of reduction in the size of seminal vesicles and hypospermatogenesis (abnormally low sperm production). The comment asserted that FDA should evaluate these effects on the male rat reproductive organs to fill the DART data gap for hexylresorcinol.

(Response 24) Although this technical report was cited in the 2013 Consumer Wash PR (78 FR 76444 at 76475, Ref. 120) for hexylresorcinol, the data in this 13-week study is not sufficient to conduct an adequate DART assessment for hexylresorcinol (Ref. 48). Specifically, the NTP report described toxicity and carcinogenicity studies of hexylresorcinol. The report consisted of three sets of studies, 16-day studies, 13-week studies, and 2-year studies, all conducted in mice and rats of both sexes. Although the findings in the 13-week studies appear to show an effect of hexylresorcinol on the reproductive system in high-dose male rats, according to the NTP report, there was no difference in the reproductive findings between controls and high-dose-treated males. No adverse findings were noted for the reproductive organs examined in males and females treated with high doses of hexylresorcinol in the 2-year carcinogenicity studies in rats and mice. However, the findings from the general toxicity studies (13-week and 2-year carcinogenicity studies) do not address all relevant reproductive and developmental endpoints for hexylresorcinol. Accordingly, we find that the safety data gap for DART for hexylresorcinol has not been adequately addressed. No new data were submitted to the docket to fill other safety data gaps identified in the 2013 Consumer Wash PR. In addition, as discussed in section IV of this document, no new data were submitted to the docket to demonstrate the effectiveness of the active ingredients subject to this final rule, including hexylresorcinol, for use as a consumer antiseptic wash product. Therefore, hexylresorcinol is not GRAS/GRAE for use in consumer antiseptic wash products.

4. Iodophors/Povidone-Iodine

In the 2013 Consumer Wash PR, we proposed to classify iodophor complexes, including povidone-iodine, 5–10 percent, as Category III, determining that the available safety and effectiveness data were insufficient and further testing was required (78 FR 76444 at 76459). FDA determined that the administrative record for the safety of iodophors was incomplete with respect to the following:

- Human studies of the absorption of iodine following maximal dermal exposure to the complexes
- Human absorption studies of the carrier molecule for small molecular weight povidone molecules and the other carriers listed in the 2013 Consumer Wash PR
- Dermal carcinogenicity studies for each of the iodophor complexes
- Data from laboratory studies that assess the potential for the development of resistance to iodine and cross-resistance to antibiotics in the types of organisms listed in the 2013 Consumer Wash PR (78 FR 76444 at 76453)

(Comment 25) One comment requested that the Agency clarify that multiuse consumer antiseptic products containing the active ingredient povidone-iodine intended for first aid use and general purpose antiseptic cleansing and labeled for only short-term use over limited areas of the skin are outside the scope of the 2013 Consumer Antiseptic PR. The comment explained that the skin cleanser's primary use is as a first aid antiseptic and it is sold in the first aid aisle of retail stores. They also explained that although the labeling provides for uses as a wash, it recommends only short term use over limited areas of the skin, consistent with the 1991 First Aid TFM; and thus, the safety studies proposed in the 2013 Consumer Wash PR should not be required for such multiuse skin cleansing products. The comments also requested that if FDA determines that multiuse antiseptic products are within the scope of the 2013 Consumer Wash PR, that a category I classification be maintained for povidone-iodine, 5–10 percent, with a molecular weight at or above 35,000 Daltons.

(Response 25) The testing requirements for a GRAS/GRAE finding as proposed in the 2013 Consumer Wash PR, apply to all consumer antiseptic wash products containing the active ingredients that are the subject of this final rule and that are intended to be used with water, such as antibacterial soaps and antibacterial hand washes (76 FR 76444 at 76446). If the labeling for these products contains an indication for use as a consumer antiseptic wash, then the product is subject to the testing requirements of the 2013 Consumer Wash PR, even if the labeling also contains an indication for other uses, such as for a first aid antiseptic.

Moreover, because consumer antiseptic washes may be used on multiple occasions throughout a person's lifetime, this use pattern is considered to be chronic. According to the International Council for Harmonization guideline, a use is considered chronic if a certain drug is used for a period of at least 6 months over the user's lifetime, including repeated, intermittent use. Thus, chronic exposure testing is necessary for a GRAS/GRAE determination for the active ingredients used in these consumer antiseptic wash products even if a particular ingredient's labeling recommends that the product's use should be limited in duration.

In addition, we decline to classify povidone-iodine 5–10 percent with a molecular weight at or above 35,000 Daltons as Category I (GRAS/GRAE) for use in consumer washes. Although we stated in the 2013 Consumer Wash PR that the larger molecular weight-size povidone molecules pose no risk of absorption, and we only requested human absorption studies of the carrier molecule for small molecular weight povidone molecules, there are still remaining safety data gaps for the iodophors, including large molecule povidone-iodine (76 FR 76444 at 76459 to 76461). For example, we determined that the administrative record for the safety of iodophors was incomplete for dermal carcinogenicity studies. Accordingly, because the safety data gaps have not been addressed, we cannot make a GRAS determination on the iodophors, including the large molecule povidone-iodine.

(Comment 26) Another comment stated that human absorption data required for the iodophors should take precedence over the requirement for dermal carcinogenicity studies to fill the safety data gaps for the iodophors. The comment argued that data from the human absorption studies may reduce the number of carcinogenicity studies needed to fill the safety data gaps for iodophors.

(Response 26) Antiseptic products, such as povidone-iodine, are applied topically and require toxicological evaluation in dermal studies to assess the potential safety signals following the exposure. The reason for requiring dermal assessment is because the skin dose resulting from a topically applied drug product can be much higher than the dose detected in the skin as a result of systemic exposure. In addition, systemic exposure to the parent drug and metabolites can differ significantly in topically applied products compared to orally administered products because the skin has its own metabolic capability, and the first-pass metabolism, which is available following oral exposure, is bypassed in the topical route of administration. In some cases, a waiver of dermal carcinogenicity may be considered for a substance used previously by another route if a chronic dermal study in an appropriate non-rodent species shows no potential neoplastic effects and there are no other causes for concern, such as absence of a positive genotoxicity signal and absence of association of exposure to the drug with a positive tumor signal in systemic carcinogenicity data (Refs. 45 and 46). Furthermore, the absence of significant systemic absorption is not a qualifying reason to waive the requirement for the dermal carcinogenicity study.

(Comment 27) A comment submitted on behalf of a marketer of an OTC antiseptic product containing povidone-iodine asserted that povidone-iodine does not pose a risk for the development of resistance (see section III.D.2 for a more general discussion on resistance). The comment noted that none of the studies cited in the 2013 Consumer Wash PR concerning the development of antiseptic/antibiotic resistance involve povidone-iodine. The comment stated that historically, povidone-iodine has not been associated with the development of resistance, and that it has been found to be a useful tool against several multidrug resistant bacteria. In support of its position, the comment submitted data on the chemistry and antimicrobial effects of povidone-iodine and studies of povidone-iodine's in vitro and in vivo effectiveness (Refs. 49 through 54).

(Response 27) Elemental iodine, which is the active antimicrobial component of iodine containing antiseptics like povidone-iodine, is generally believed to be nonspecific in its antimicrobial action (Ref. 55). The antimicrobial activity of iodine is caused by its oxidizing effects on amino (NH-), thiol (SH-), phenolic hydroxyl (OH-) groups of amino acids and nucleotides. These reactions lead to a loss in protein structure and function and an inhibition of protein synthesis. Iodine also reacts with the double bonds of unsaturated fatty acid components of cell wall and organelle membranes, compromising the integrity of these structures. The effects of povidone-iodine on cell ultrastructure have been observed at concentrations as low as 0.025 percent povidone-iodine in *Staphylococcus aureus, Esherichia coli,* and *Candida albicans* (Ref. 49). A decrease in enzyme (β-galactosidase) activity and nucleotide efflux was also apparent at 0.42 and 0.83 percent povidone-iodine (Ref. 49). These concentrations are well below the concentrations of povidone-iodine found in currently marketed products.

A search of the published literature revealed two studies that attempted to select for resistant bacterial strains after repeated exposure to sublethal concentrations of povidone-iodine (Refs. 56 and 57). Houang et al. studied the potential for the development of resistance to povidone-iodine by serial passage of two strains of each of the following organisms: *Escherichia coli, Klebsiella aerogenes,* and one strain of *Serratia marcescens* in sub-inhibitory concentrations (Ref. 56). The authors reported no significant differences in MIC, minimum bactericidal concentration, or killing time after 20 passages. Similarly, Prince et al. reported that they had failed to detect any changes in the MIC of six Gram-negative bacteria (*Proteus mirabilis, Serratia marcescens, Serratia rubidaea, Pseudomonas cepacia (now known as Burkholderia cepacia), Pseudomonas aeruginosa,* and *Salmonella enteritidis*) after 20 serial passages in povidone-iodine (Ref. 57).

The search also revealed some reports of *Burkholderia cepacia* contamination of povidone-iodine products (Refs. 58 through 62). However, the antiseptic susceptibilities of the organisms isolated were never established, making it hard to determine whether the contamination was the result of an existing intrinsic antiseptic resistance that has been associated with *Burkholderia cepacia* or the development of an increased tolerance. In addition, the literature search revealed no reports of the development of resistance to povidone-iodine. Consequently, given iodine's multiple nonspecific toxic effects on bacteria at low concentrations and the lack of reports of the development of resistance to iodine, there currently are insufficient data on which to base a concern about the development of resistance to povidone-iodine. Consequently, additional data on the development of antimicrobial resistance to povidone-iodine are not needed to make a GRAS determination.

5. Triclocarban

In the 2013 Consumer Wash PR, FDA proposed to classify triclocarban as Category III for safety and efficacy (78 FR 76444 at 76449). FDA determined that the administrative record for the safety of triclocarban was incomplete with respect to the following:

- Human pharmacokinetic studies under the maximal use conditions when applied topically, including documentation of validation of the methods used to measure triclocarban and its metabolites
- Animal pharmacokinetic studies on ADME
- Data to help define the effect of formulation on dermal absorption
- Dermal carcinogenicity
- Developmental and reproductive toxicity data
- Potential hormonal effects
- Data from laboratory studies that assess the potential for the development of resistance to triclocarban and cross-resistance to antibiotics in the types of organisms listed in section VII.C.3 of the 2013 Consumer Wash PR (78 FR 76444 at 76456 to 76462)

(Comment 28) One comment referenced a DART study conducted by Monsanto in 1979. The study was summarized in a triclocarban data set compiled in 2002 by the Triclocarban (TCC) Consortium and the Soap and Detergent Association. The comment requested that FDA evaluate the results of the study to fill the DART safety gap for triclocarban.

(Response 28) The TCC Consortium Report was retrieved from the Environmental Protection Agency (EPA) High Production Volume Information System Web site. We were unable to locate the 1979 Monsanto study in the docket and it does not appear to be available in the public domain. Thus, we cannot review this study for purposes of this final rule. The data cited in the TCC Consortium data set are proprietary and are publicly available only in the form of a summary (Ref. 63). In addition, the submitted safety assessments with the study summaries do not constitute an adequate record on which to base a GRAS classification (§ 330.10(a)(4)(i)). For FDA to evaluate the safety of triclocarban for this rulemaking, there must be published studies or publicly available data with sufficient details that enable an independent review of such data.

(Comment 29) One comment also stated that triclocarban was nominated to the NTP for toxicological evaluation in 2014, and based on this nomination, a Research Concept has been adopted by NTP (Ref. 64). The comment asserted that the author of the Triclocarban Research Concept only discussed FDA's proposal in regard to human absorption studies even though it identified several data gaps that were identified by FDA, including ADME and DART studies. The comment concluded that FDA should coordinate its efforts with those of the NTP to ensure that experiments on the toxicological testing of triclocarban are not being duplicated.

(Response 29) We concur with the comment that FDA should coordinate efforts with NTP. NTP through collaboration with FDA regularly meets with FDA scientists to coordinate research efforts and eliminate duplicative work whenever possible. Although this ongoing study may provide important information on triclocarban, there are still other missing data gaps for triclocarban for which information has not been submitted and no interested parties have committed to filling these data gaps. Accordingly, deferring consideration of this active ingredient until the study is completed is unwarranted.

In conclusion, we find that the safety data gap for DART for triclocarban has not been adequately addressed. No new data for triclocarban were submitted to the docket to fill other safety data gaps identified in the 2013 Consumer Wash PR. In addition, as discussed in section IV, no new data were submitted to the docket to demonstrate the effectiveness of the active ingredients subject to this final rule, including triclocarban, for use as a consumer antiseptic wash product. Therefore, triclocarban is not considered GRAS/GRAE for use in consumer antiseptic wash products.

6. Triclosan

In the 2013 Consumer Wash PR, the Agency found that the administrative record for triclosan was incomplete with respect to several safety data and requested that additional information be submitted for the following safety gaps (76 FR 76444 at 76467 to 76470):

- Animal ADME
- Dermal carcinogenicity
- Data regarding the potential for formation of photodegradation products on human skin and their effects on the skin
- Potential hormonal effects
- Data to clarify the relevance of antimicrobial resistance laboratory findings to the consumer setting

(Comment 30) In response to the 2013 Consumer Wash PR, several comments were submitted regarding the safety data gaps for triclosan. One comment argued that recent and existing studies on triclosan in each of the safety categories prove that the existing studies, including additional studies that were not cited in the 2013 Consumer Wash PR, are adequate to classify triclosan as GRAS.

(Response 30) FDA has conducted a thorough review of all existing and new data that have been submitted to the docket for this rulemaking, including recent studies, as well as opinion papers published by other regulatory agencies regarding the safety of triclosan. In some cases, we identified new data that have been published since the 2013 Consumer Wash PR—for example, the new animal ADME dermal data discussed in the following section. In other cases, no new data having an impact on the safety profile of triclosan were identified—for example, we found that certain references submitted in one of the comments did not provide additional information that would have an impact on the safety assessment of triclosan (Refs. 65 through 67). In sum, the total available data regarding the safety profile of triclosan does not contain sufficient information to determine that triclosan is GRAS for use in consumer antiseptic wash products.

In the following sections, we discuss comments addressing the specific safety data gaps for triclosan.

a. Absorption, Distribution, Metabolism, and Excretion (ADME) Data

The 2013 Consumer Wash PR discussed in detail the animal ADME data available for triclosan (78 FR 76444 at 76467) and the data that were still lacking. FDA requested that additional ADME data be submitted to allow bridging of animal data to human exposure.

(Comment 31) Several comments were submitted regarding animal ADME data for triclosan. Some of the comments asserted that oral absorption, metabolism, and excretion are comparable between hamsters and humans, justifying data extrapolation. They also asserted that oral absorption data are complete in all species tested and that metabolism is similar for both dermal and oral exposure. In addition, some of the comments urged FDA to evaluate key toxicokinetic studies in hamsters, mice, and rats that have been submitted as part of the European Union's Registration, Evaluation, Authorisation, and Restriction of Chemicals registration, as well as evaluate other referenced publications of regulatory agencies.

(Response 31) We agree that there are a number of similarities in pharmacokinetic parameters between humans and hamsters; however, the hamster data available do not include dermal ADME data that can be compared to the metabolic profile in humans following dermal exposure to triclosan.

We have reviewed data that were submitted to the docket for this rulemaking, including recent studies that were published after the 2013 Consumer Wash PR, as well as opinion papers published by other regulatory agencies regarding the safety of triclosan (Ref. 68). With the exception of one study that we have identified that provided new animal dermal ADME data, there were no additional ADME data for triclosan that were submitted to the docket. The ADME study that was identified has been recently published by National Center for Toxicology Research (NCTR) scientists (Ref. 68) where a 13-week dermal-dose range-finding toxicity study was conducted to determine the ADME profile of triclosan after dermal exposure in mice. Based on a previous dermal toxicity study in the mouse where a no observed adverse effect level of 12.5 milligram (mg)/kilogram (kg) of body weight (bw)/day was shown, doses of 10 and 100 mg/kg bw triclosan were used. In this study, mice of both sexes were exposed to topical application of [^{14}C(U)]triclosan (10 or 100 mg triclosan/kg body weight) in 95 percent ethanol up to 72 hours post exposure. Treated mice were covered with Elizabethan collars to prevent inadvertent oral ingestion of triclosan. As a comparator group, mice of both sexes were dosed with 100 mg/kg bw where Elizabethan collars were not placed on their necks to determine the extent of oral ingestion because of the normal grooming behavior in mice. The study reported a dose-dependent increase in absorption was noted when comparing the 10 mg/kg bw to the 100 mg/kg bw. The study also reported that distribution of radiolabeled [^{14}C(U)]triclosan was evaluated to determine distribution up to 72 hours after dosing in the plasma and liver. The earliest radioactivity measureable was seen as early as 30 minutes post dosing, while maximum distribution was reached at approximately 8 to 12 hours after dosing for both plasma and liver. The major metabolite detected in the plasma and liver was triclosan sulfate, whereas the minor metabolite was triclosan glucuronide. Maximum levels occurred 12 to 24 hours after dosing, and the excretion half-life ($t_{1/2E}$) ranged from 9.3 to 23.1 hours. The study also reported that the majority of the excretion monitored over 72 hours occurred via the feces in both sexes and that fecal excretion of the absorbed triclosan was ~2.5 to 6-fold greater than urinary excretion.

The data obtained from this study can be used to extrapolate a safety margin for humans following chronic dermal exposure once the dermal carcinogenicity study in the mouse, which is currently ongoing at the NCTR, is completed. No further data is needed for the animal ADME for triclosan.

b. Photodegradation and Phototoxicity

(Comment 32) Several comments were submitted regarding the phototoxicity of triclosan. One comment explained that a study is currently ongoing at the NTP in response to the data gap on dermal photocarcinogenicity from dioxins formed by light-induced degradation of triclosan. The comments urged FDA to await the results of this study before any further studies are conducted. Two other comments argued that concern about triclosan dermal photolysis to "dioxins" is unfounded, and that the most likely photolysis product, 2, 8-dichlorbenzodioxin is toxicologically inert based on the toxicology equivalency factor (TEF) concept (which compares the toxicity of known members for a given chemical family and attributes a specific TEF for each compound compared to the most toxic chemical of that family).

(Response 32) We note that the comments did not provide any further justification or calculation of the TEF for the photolysis product, 2, 8-dichlorbenzodioxin, to support the claim that FDA's concern about triclosan dermal photolysis to "dioxins" is unfounded. Instead, an assumption was made that 2, 8-dichlorbenzodioxin is toxicologically inert based on the TEF concept. The TEF concept refers only to adverse effects (*e.g.*, cancer) following interactions with their targets (*e.g.*, cellular aryl hydrocarbon receptors). Other toxic effects of dioxins and dioxin-like compounds are not quantified by this method. In addition, TEF values vary for different animal species. Therefore, the ability of triclosan degradants, which belong to the dioxin family, to form photodegradation products on human skin cannot be assessed using the TEF concept. Furthermore, it is currently unknown whether the photoactivity of triclosan is caused by one of the photoproducts or caused by the interaction of triclosan itself with ultraviolet (UV) light.

(Comment 33) Another comment stated that triclosan has been found to degrade into four different byproducts under certain conditions: 2, 7-dibenzodichloro-p-dioxin; 2, 8-dibenzodichloro-p-dioxin; 2, 4-dichlorophenol (DCP); and 2, 4, 6-trichlorophenol (TCP). In the presence of UV light (sunlight), triclosan has been shown to degrade into two dioxins: 2, 7-dibenzodichloro-p-dioxin; and 2, 8-dibenzodichloro-p-dioxin. The comment suggested that although the concentrations of the degradants are low, dioxin byproducts raise some concern because of their potential to accumulate in the human body because of their lipophilicity. Both 2, 4-DCP and 2, 4, 6-TCP are more stable than triclosan, suggesting that the degradants may have longer half-lives than the parent drug, triclosan.

(Response 33) Regardless of the causative chemical, it is unknown at this time whether exposure to triclosan under UV light will lead to phototoxicity or photocarcinogenicity events. In conclusion, the comments provided insufficient data and information for assessing the photodegradation of triclosan on human skin. Accordingly, the safety data gap for triclosan regarding the potential for formation of photodegradation products on human skin and their effects on the skin has not been filled.

c. Dermal Carcinogenicity

(Comment 34) Several comments were received regarding the dermal carcinogenicity of triclosan. One comment argued that, based on FDA and EPA assessments, oral carcinogenicity studies in hamsters, rats, and mice, supported by negative in vitro and in vivo mutagenicity studies show that triclosan is not a carcinogen. Therefore, the comments argued that the ongoing dermal carcinogenicity study is unnecessary. Another comment stated that dermal carcinogenicity is not supported by existing data, and no chemical having negative mutagenicity and oral carcinogenicity data should be expected to demonstrate dermal carcinogenicity potential.

(Response 34) We disagree that no dermal carcinogenicity study is needed for triclosan based only on the negative mutagenicity and oral carcinogenicity studies. The requirement for dermal assessment is based on several factors: First, the dose available to the skin tissue resulting from a topically applied drug product can be much higher than that from a dose resulting from systemic exposure. In addition, systemic exposure to the parent drug and metabolites can differ significantly in topically applied products compared to orally administered products because the skin has its own metabolic capability, and the first-pass metabolism, which is available following oral exposure, is bypassed in the topical route of administration. As was explained in the 2013 Consumer Wash PR, we reiterate here that short-term dermal toxicity studies do not meet the chronic duration requirement for a given drug to cause an increase in the carcinogenic potential resulting from a lifelong exposure to a drug, such as triclosan, which is used by consumers from various products over a lifetime. In addition, we note that the 13-week dermal toxicity study showed dose-related dermal adverse effects, which further amplifies the need to evaluate longer term toxicity studies, such as the 2-year dermal carcinogenicity bioassay. A dermal carcinogenicity study is currently ongoing at NCTR but has not been completed at this time. Although this ongoing study may provide important information on triclosan, there are still other missing data gaps for triclosan for which information has not been submitted and no interested parties have committed to filling these data gaps. In sum, no new data or information were submitted to the docket to fill the dermal carcinogenicity safety data gap for triclosan.

d. Hormonal Effects

In the 2013 Consumer Wash PR, we stated that recent studies have demonstrated that triclosan showed effects on the thyroid, estrogen, and testosterone systems in several animal species, including mammals, the implications of which on human health, especially for children, are still not well understood (78 FR 76444 at 76468).

(Comment 35) One comment stated that the Organisation for Economic Co-operation and Development (OECD) TG 443 extended one-generation reproductive toxicity assay provides an alternative to animal studies and includes endocrine-sensitive endpoints. The comment asserted that the OECD TG 443 study design allows for investigation of developmental toxicity, developmental immunotoxicity, or developmental neurotoxicity in the same study, and that non-animal methods, when used in an integrated system, can provide embryotoxicity and teratogenicity information. The comment also referenced several other non-animal assays that were conducted to assess the reproductive toxicity potential for triclosan.

(Response 35) We reviewed all available data on the hormonal effects of triclosan, including those generated from the extended one-generation reproductive toxicity assay mentioned previously in this document. We also reviewed the previously conducted studies for triclosan (general toxicity and reproductive toxicity) where reproductive toxicity endpoints were evaluated; however, we note that the previously conducted studies were not designed to investigate specific endpoints for evaluating the hormonal effects of triclosan, especially with respect to the thyroid findings. In terms of the alternative animal model argument, it is possible that in some instances that non-animal assays, such as those referenced in comment 35, can be used to explore potential DART findings for a new chemical entity. However, in the case of triclosan, there are many in vivo studies that have assessed DART endpoints, thus making the reliance on findings from the referenced non-animal assays unnecessary.

(Comment 36) Several other comments asserted that the existing database of in vitro and in vivo animal and human studies does not support a conclusion that triclosan causes hormonal effects in humans at actual relevant exposure concentrations. The comments asserted that the reports of high throughput screening and animal studies showing thyroid or other hormonal activity demonstrated conflicting results for the effects of triclosan on various hormonal endpoints (androgen-, estrogen-, and thyroid-related toxicity). One comment also argued that additional testing for potential hormonal effects is not justified because of the existence of adequate reproductive toxicity data that, given the doses used, endpoints measured and study duration, should have detected a potential for the indication of biologically significant androgen-, estrogen-, or thyroid-related toxicity if such toxicity occurred. The comment maintained that available in vitro high throughput screen information on these endpoints fails to indicate a justifiable level of concern.

(Response 36) We agree that some data for hormonal effects for triclosan can be gleaned from previously conducted studies (chronic toxicity, DART, and multigenerational studies). Although we concur that the previously conducted toxicology and reproductive studies can be useful, we note that the previously conducted studies were not designed to investigate specific endpoints for evaluating the hormonal effects of triclosan. In particular, the effects of triclosan on the thyroid gland during critical windows of growth and development when subtle functional and/or histopathologic changes are taking place could result in disturbing the normal homeostasis of the organism; for example, whether long-term exposure to triclosan is associated with an adverse impact on the growth or neurobehavioral aspects of animals treated during critical windows of development is currently unknown.

We have evaluated the recently published articles in the literature reporting on the endocrine effects of triclosan in mammalian species. Data available to date do not provide conclusive evidence regarding the effects of triclosan on the levels of estrogen, androgen, and thyroid hormones and whether a link between the hormonal effects and the biologically relevant outcomes on the tested animal model can be drawn. Although no significant findings were noted for reproductive endpoints, the thyroid gland may be a potential target for triclosan in animals exposed to high doses of triclosan. The reported findings in the thyroid included a dose dependent decrease in the levels of some thyroid hormones in the rat model (T_3 & T_4) (Ref. 69). This observation was seen in pubertal males and females, in pregnant dams and their pre-weaned exposed pups, as well as in young male and female rats (up to day 53 postpartum age). It is also important to note that the available rat studies for which the thyroid effects were investigated in detail only covered a short duration (up to 30 days of exposure). These changes seen in thyroid hormone levels in the rat do not necessarily predict a similar scenario in humans because of differences in the physiology and metabolic characteristics that triclosan imparts on the hormonal homeostasis in the two species. Based on the available data, a conclusion regarding the significance of the thyroid findings in the rat to that in humans cannot be made. Using a weight-of-evidence approach for the thyroid findings, we find that no further nonclinical data are recommended for the characterization of potential hormonal effects of triclosan in humans. Available in vitro and in vivo animal studies cannot be used to predict a potential human hormonal signal. Clinical studies may be better able to evaluate the effects of triclosan on the endocrine system in humans.

e. Resistance

(Comment 37) Comments from a manufacturer of consumer antiseptic products containing triclosan asserted that there is no proof of triclosan resistance or confirmation that triclosan/antibiotic cross-resistance is becoming a problem in the real world. The comment also noted that although bacteria can develop reduced susceptibilities to triclosan in the laboratory, the level of sensitivity is still well below the at-use concentration. However, other comments disagreed and argued that recent studies provide evidence of the development of resistance to triclosan (Refs. 29 and 30).

(Response 37) We agree that currently there is no evidence of bacterial resistance to actual-use concentrations of triclosan. However, bacterial exposure to triclosan is not limited to actual-use concentrations. In a natural setting, bacteria are exposed to sublethal concentrations of the antiseptic active ingredient that can trigger the expression of bacterial resistance mechanisms. The European Commission's Subcommittee on Consumer Safety noted that there are environmental concentrations of triclosan in a number of geographically distinct areas that were high enough to suggest that this triggering of bacterial resistance could occur (Ref.70). Furthermore, as previously discussed, there are data that document the existence of numerous bacterial resistance mechanisms to triclosan, and there is some expression of these mechanisms in the natural microbial populations. Although the available studies do not prove definitively that triclosan/antibiotic resistance currently poses a public health risk, they do suggest that susceptibility to triclosan may be decreasing. Data are not currently available to assess the magnitude of this risk that triclosan poses for the development of resistance. As we stated in the in the 2013 Consumer Wash PR, data to clarify the relevance of antimicrobial resistance laboratory findings to the consumer setting would be necessary to determine the GRAS status of triclosan.

f. Other Issues

(Comment 38) Several comments expressed concern that antiseptic chemicals, including triclosan, are contaminating waterways and aquatic wildlife, and are having a negative impact on the wastewater treatment process and the environment. The comments supported restrictions on the use of triclosan in consumer antiseptic washes and urged FDA and EPA to coordinate their evaluation of chemicals like triclosan to better protect human health and the environment, as well as protect the wastewater treatment process.

(Response 38) We do not address these comments in this final rule because they are outside the scope of this rulemaking. We note, however, that we have conferred with EPA, wherever there were issues in common between the two Agencies (*e.g.,* some of the animal toxicology studies were independently reviewed by both EPA and FDA), at various stages of the antiseptic proceedings on matters applicable to these rulemakings.

In sum, the total available data regarding the safety profile of triclosan do not contain sufficient information to find that triclosan is GRAS for use in consumer antiseptic wash products. Moreover, we reviewed studies submitted in the comments to support efficacy for triclosan. These studies are not designed as adequate and well-controlled clinical outcome studies and are not sufficient to determine the GRAE status of triclosan as a topical antiseptic. Moreover, these studies lack an adequate vehicle or placebo controls, which makes it difficult to determine the contribution of antiseptic hand wash implementation to reduction of methicillin-resistance *Staphylococcus aureus* infections. Thus, we find that insufficient data were submitted to the docket to demonstrate the effectiveness of triclosan for use as a consumer antiseptic wash product. Therefore, triclosan is not GRAS/GRAE for use in consumer antiseptic wash products.

F. Comments on the Preliminary Regulatory Impact Analysis and FDA Response

(Comment 39) Several comments raised issues concerning the preliminary regulatory impact analysis and the Agency's assessment of the net benefit of the rulemaking.

(Response 39) Our response is provided in the full discussion of economic impacts, available in the docket for this rulemaking (Docket No. 1975–N–0012, *http://www.regulations.gov*) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

IV. Ingredients Not Generally Recognized as Safe and Effective

In addition to the individual active ingredients discussed in section III.E, no additional safety or effectiveness data have been submitted to support a GRAS/GRAE determination for the remaining consumer antiseptic wash active ingredients. Thus, the following active ingredients are not GRAS/GRAE for use as a consumer antiseptic wash:

- Cloflucarban
- Fluorosalan
- Hexachlorophene
- Hexylresorcinol
- Iodophors (Iodine-containing ingredients)
  - Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)
  - Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)
  - Nonylphenoxypoly (ethyleneoxy) ethanoliodine
  - Poloxamer—iodine complex
  - Povidone-iodine 5 to 10 percent
  - Undecoylium chloride iodine complex
- Methylbenzethonium chloride
- Phenol (greater than 1.5 percent)
- Phenol (less than 1.5 percent)
- Secondary amyltricresols
- Sodium oxychlorosene
- Tribromsalan
- Triclocarban
- Triclosan
- Triple dye

Accordingly, OTC consumer antiseptic wash drug products containing these active ingredients are misbranded, and are new drugs for which approved new drug applications are required for marketing.

V. Effective Date

In the 2013 Consumer Wash PR, we recognized, based on the scope of products subject to this final rule, that manufacturers would need time to comply with this final rule. Thus, as proposed in the 2013 Consumer Wash PR (78 FR 76444 at 76470), this final rule will be effective 1 year after the date of the final rule's publication in the **Federal Register**. On or after that date, any OTC consumer antiseptic wash drug product containing an ingredient that we have found in this final rule to be not GRAS/GRAE or to be misbranded, cannot be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved new drug application.

VI. Economic Analysis of Impacts

The summary analysis of benefits and costs included in this final rule is drawn from the detailed Regulatory Impact Analysis that is available at *http://www.regulations.gov,* Docket No. FDA–1975–N–0012 (formerly Docket No. 1975N–0183H).

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The Office of Management and Budget (OMB) has determined that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because a majority of firms that will be affected by this rule are defined as small businesses, we find that the final rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

As discussed in the preamble of this final rule, this rule establishes that 19 active ingredients, including triclosan and triclocarban, are not generally recognized as safe and effective and are misbranded for use in OTC consumer antiseptic washes. Regulatory action is being deferred on three active ingredients that were included in the 2013 Consumer Wash PR: Benzalkonium chloride, benzethonium chloride, and chloroxylenol. The costs and benefits of the final rule are summarized in table 3, entitled *Economic Data: Costs and Benefits Statement.* As table 3 shows, the primary estimated benefits come from reduced exposure to antiseptic active ingredients by 2.2 million pounds per year. We note that triclosan and triclocarban, are the most widely used OTC consumer antiseptic wash active ingredients on the market, based on available data, thus, our analysis focuses on these two products. Using the primary estimates, the combined total consists of a reduction in triclosan exposure by 799,426 pounds per year, and triclocarban exposure by 1.4 million pounds per year. Limitations in the available data characterizing the health effects resulting from widespread long-term exposure to these ingredients prevent us from translating the estimated reduced exposure into monetary equivalents of health effects.

The primary estimate of costs annualized over 10 years is approximately $23.6 million at a 3 percent discount rate and $27.6 million at a 7 percent discount rate. These costs consist of total one-time costs of relabeling and reformulation ranging from $106.3 to $402.8 million. Under the final rule, we estimate that each pound of reduced exposure to antiseptic active ingredients will cost $12.97 to $14.28 at a 3 percent discount rate and $16.36 to $18.02 at a 7 percent discount rate.

TABLE 3—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT

Economic Data: Costs and Benefits Statement							
				Units			
Category	Primary estimate	Low estimate	High estimate	Year dollars	Discount rate (%)	Period covered	Notes
Benefits							
Annualized Monetized $millions/year.	....	....	....	....	7	Annual.	
	....	....	....	....	3	Annual.	
Annualized Quantified	2,197,737	989,856	3,405,619	....	7	Annual ..	Reduced antiseptic active ingredient exposure (in pounds).
	2,197,737	989,856	3,405,619	....	3	Annual.	
Qualitative	....	....	....	....	....		
Costs							
Annualized Monetized $millions/year.	27.6	14.1	53.6	2014	7	Annual ..	Annualized costs of relabeling and reformulation. Range of estimates captures uncertainty.
	23.6	12.1	45.8	2014	3	Annual.	
Annualized Quantified	....	....	....	....	7		
	....	....	....	....	3		
Qualitative	....	....	....	....	....		
Transfers							
Federal Annualized Monetized $millions/year.	....	....	....	....	7	....	None.
	....	....	....	....	3		
From/To	From:			To:			
Other Annualized Monetized $millions/year.	....	....	....	....	7		
	....	....	....	....	3		
From/To	From:			To:			
Effects							
State, Local, or Tribal Government: Not applicable.							
Small Business							
Annual cost per affected small entity estimated as $0.11–$0.41 million, which will represent 0.28–1.10 percent of annual shipments.							
Wages: No estimated effect.							
Growth: No estimated effect.							

The full analysis of economic impacts is available in the docket for this final rule (Docket No. FDA–1975–N–0012) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to "construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." The sole statutory provision giving preemptive effect to the final rule is section 751 of the FD&C Act (21 U.S.C. 379r). We have complied with all of the applicable requirements under the Executive order and have determined that the preemptive effects of this rule are consistent with Executive Order 13132.

X. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified all Web site addresses as of the date of this document, but Web sites are subject to change over time.

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2. Comment submitted in Docket No. FDA–1975–N–0012, available at *http://www.regulations.gov* with Comment No. FDA–1975–N–0012–0081.
3. Transcript of the March 23, 2005, Nonprescription Drugs Advisory Committee. Available at *http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4184T1.pdf.*
4. Transcript of the October 20, 2005, Meeting of the Nonprescription Drugs Advisory Committee 2005. Available at *http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4184T1.pdf.*
5. Summary Minutes of the November 14, 2008, Feedback Meeting with Personal Care Products Council and Soap and Detergent Association, OTC Vol. 230002. Available at *https://www.regulations.gov/document?D=FDA-1980-N-0006-0031.*
6. Transcript of the September 3, 2014, Meeting of the Nonprescription Drugs Advisory Committee 2014. Available at *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/UCM421121.pdf.*
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List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

■ 1. The authority citation for part 310 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 360hh–360ss, 361(a), 371, 374, 375, 379e, 379k–l; 42 U.S.C. 216, 241, 242(a), 262.

■ 2. In § 310.545, add paragraphs (a)(27)(iii) and (iv) and (d)(41), and remove from paragraph (d) introductory text the number "(39)" and add in its place the number "(41)" to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(27) * * *

(iii) *Consumer antiseptic hand wash drug products.* Approved as of September 6, 2017.

Cloflucarban
Fluorosalan
Hexachlorophene
Hexylresorcinol
Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)
Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)
Methylbenzethonium chloride
Nonylphenoxypoly (ethyleneoxy) ethanoliodine
Phenol (greater than 1.5 percent)
Phenol (less than 1.5 percent)
Poloxamer iodine complex
Povidone-iodine (5 to 10 percent)
Secondary amyltricresols
Sodium oxychlorosene
Tribromsalan
Triclocarban
Triclosan
Triple Dye
Undecoylium chloride iodine complex

(iv) *Consumer antiseptic body wash drug products.* Approved as of September 6, 2017.

Cloflucarban
Fluorosalan
Hexachlorophene
Hexylresorcinol
Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)
Iodine tincture
Methylbenzethonium chloride
Nonylphenoxypoly (ethyleneoxy) ethanoliodine
Phenol (greater than 1.5 percent)

Phenol (less than 1.5 percent)
Poloxamer iodine complex
Povidone-iodine (5 to 10 percent)
Secondary amyltricresols
Sodium oxychlorosene
Tribromsalan
Triclocarban
Triclosan
Triple Dye
Undecoylium chloride iodine complex

* * * * *

(d) * * *

(41) September 6, 2017, for products subject to paragraph (a)(27)(iii) or (iv) of this section.

Dated: August 31, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21337 Filed 9–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–433]

Schedules of Controlled Substances: Placement of PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule I of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA.

DATES: *Effective date:* September 6, 2016.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purposes of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II.

The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308. 21 U.S.C. 812(a).

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, "add to such a schedule or transfer between such schedules any drug or other substance if he * * * finds that such drug or other substance has a potential for abuse, and * * * makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *." The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA, 28 CFR 0.100, who in turn has redelegated that authority to the Deputy Administrator of the DEA, 28 CFR part 0, appendix to subpart R.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on her own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS); [1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated by the former Deputy Administrator of the DEA on his own motion and is supported by a recommendation from the Assistant Secretary of the HHS and an evaluation of all other relevant data by the DEA. This action imposes the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles, or proposes to handle, PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA.

Background

On January 10, 2014, the DEA published a notice of intent to temporarily place quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) into schedule I pursuant to the temporary scheduling provisions of the CSA. 79 FR 1776. On February 10, 2014, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these four synthetic cannabinoids into schedule I of the CSA. 79 FR 7577. That final order was effective on the date of publication, and was based on findings by the DEA that the temporary scheduling of these four synthetic cannabinoids was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1).

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[1] As set forth in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993. Accordingly, all subsequent references to "Secretary" have been replaced with "Assistant Secretary."

Section 201(h)(2) of the CSA requires that the temporary control of these substances expires two years from the effective date of the scheduling order, or on or before February 9, 2016. 21 U.S.C. 811(h)(2). However, the CSA also provides that the temporary scheduling may be extended for up to one year during the pendency of proceedings under 21 U.S.C. 811(a)(1). *Id.* Accordingly, on February 5, 2016, the DEA extended the temporary scheduling of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA by one year, until February 9, 2017. 81 FR 6175. Also, on February 5, 2016, DEA published a notice of proposed rulemaking (NPRM) to permanently control PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA in schedule I of the CSA. 81 FR 6190.

DEA and HHS Eight Factor Analyses

On January 19, 2016, the HHS provided the DEA with four scientific and medical evaluation documents prepared by the FDA entitled "Basis for the recommendation to place 1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester or quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22) and its salts in Schedule 1 of the Controlled Substances Act (CSA);" "Basis for the recommendation to place quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5F-PB-22) and its salts in Schedule 1 of the Controlled Substances Act (CSA);" "Basis for the recommendation to place *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and its salts in Schedule 1 of the Controlled Substances Act (CSA);" and "Basis for the recommendation to place *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) and its salts in Schedule 1 of the Controlled Substances Act (CSA)." After considering the eight factors in 21 U.S.C. 811(c), including consideration of each substance's abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA be controlled in schedule I of the CSA. In response, the DEA conducted its own eight-factor analysis of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA and concluded that these substances warrant control in schedule I of the CSA. Both the DEA and HHS analyses are available in their entirety in the public docket for this rule (Docket Number DEA–433/DEA–2016–0002) at *http://www.regulations.gov* under "Supporting Documents."

Determination To Schedule PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA

After a review of the available data, including the scientific and medical evaluations and the scheduling recommendations from the HHS, the DEA published an NPRM entitled "Schedules of Controlled Substances: Placement of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA into Schedule I," proposing to control PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA in schedule I of the CSA. 81 FR 6190. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with the DEA regulations on or before March 7, 2016. No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before March 7, 2016.

Comments Received

The DEA received three comments on the proposed rule to control PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA in schedule I of the CSA.

1. *Request for Alternate Manufacturing/Packaging of Opiate Pills:* One commenter stated that alternate manufacturing and packaging of opiate pills would reduce access to these drugs. The comment was addressed to the FDA.

- *DEA Response:* PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA are synthetic cannabinoid substances. Opiate pills are not addressed or affected by this rulemaking.

2. *Support for rulemaking:* One commenter gave support for the rulemaking stating that the rule was a step in the right direction.

- *DEA Response:* The DEA appreciates the comment in support of this rulemaking.

3. *Mixed Support and Dissent:* One commenter supported in part and dissented in part, suggesting that research into potential medical uses of these substances be conducted prior to scheduling.

- *DEA Response:* On February 10, 2014, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these four synthetic cannabinoids into schedule I of the CSA. 79 FR 7577. That final order was based on findings by the DEA that the temporary scheduling of these four synthetic cannabinoids was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Adverse effects following ingestion of these substances have included: Seizures, neurotoxicity, and death for PB-22; respiratory failure, organ failure, and death for 5F-PB-22; diaphoresis, nausea, confusion, tachycardia, and death for AB-FUBINACA; and anxiety, delirium, psychosis, aggression, and seizures for ADB-PINACA. There is no currently accepted medical use for these four substances in treatment in the United States, and the substances fulfill all requirements for placement into schedule I of the CSA.

After considering the eight factors in 21 U.S.C. 811(c), including consideration of each substance's abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA be controlled in schedule I of the CSA. In response, the DEA reviewed the scientific and medical evaluations of HHS and all other relevant data on PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA and concurs with the HHS evaluations and findings. The current scientific, medical and other evidence on PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA warrant control of these substances in schedule I of the CSA.

Scheduling Conclusion

Based on consideration of all comments, the scientific and medical evaluations and accompanying recommendations of the HHS, and the DEA's consideration of its own eight-factor analyses, the DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA. As such, the DEA is scheduling PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA as controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analyses and recommendations of the Assistant Secretary for HHS and review of all other available data, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

(1) quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-

pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) have a high potential for abuse that is comparable to other schedule I substances such as delta-9-tetrahydrocannabinol (Δ^9-THC) and JWH-018;

(2) quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) have no currently accepted medical use in treatment in the United States; and

(3) There is a lack of accepted safety for use of quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) under medical supervision.

Based on these findings, the Administrator of the DEA concludes that quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) including their salts, isomers and salts of isomers, including optical, positional and geometric isomers, whenever the existence of such salts, isomers, salts of isomers, optical isomers, positional isomers, and geometric isomers is possible, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA

Upon the effective date of this final rule, any person who handles PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA continues[2] to be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research and conduct of instructional activities or chemical analysis, and possession of schedule I controlled substances, including those listed below. These controls will continue on a permanent basis:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA, or who desires to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312 as of September 6, 2016. Any person who currently handles PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA and is not registered with the DEA must submit an application for registration and may not continue to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA as of September 6, 2016 unless the DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of Stocks.* PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA continue to be subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823, and and in accordance with 21 CFR 1301.71–1301.93 as of September 6, 2016.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA must continue to comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302 as of September 6, 2016.

5. *Quota.* Only registered manufacturers are permitted to manufacture PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of September 6, 2016.

6. *Inventory.* Every DEA registrant whose registration currently authorizes handling of these substances and who possesses any quantity of PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA on the effective date of this final rule is required to continue to maintain an inventory of all stocks of PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with the DEA on or after the effective date of the final rule is required to take an initial inventory of all stocks of PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA on hand pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA) on hand every two years pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317 as of September 6, 2016. Manufacturers and distributors must submit reports regarding PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA to the Automation of Reports and Consolidated Order System (ARCOS) pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304 and 1312 as of September 6, 2016.

8. *Order Forms.* Every DEA registrant who distributes PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA must continue to comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305, as of September 6, 2016.

9. *Importation and Exportation.* All importation and exportation of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA must continue to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312 as of September 6, 2016.

10. *Liability.* Any activity involving PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA not authorized by, or in violation of, the CSA or its implementing regulations continues to be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

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[2] PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 81 FR 6175, Feb. 5, 2016.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On February 10, 2014, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these four synthetic cannabinoids into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 79 FR 7577. On February 5, 2016, the DEA published a final order extending the temporary placement of these substances in schedule I of the CSA for up to one year pursuant to 21 U.S.C. 811(h)(2). 81 FR 6175. Accordingly, all entities that currently handle or plan to handle these synthetic cannabinoids are estimated to have already established and implemented the systems and processes required to handle PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA. Therefore, the DEA anticipates that this rule will impose minimal or no economic impact on businesses that currently handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA for lawful purposes. This estimate applies to entities large and small. Accordingly, the DEA has concluded that this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the "Regulatory Flexibility Act" section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, that this action will not result in any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: "an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets." However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. Amend § 1308.11 as follows:

■ a. Add paragraphs (d)(51) through (54);

■ b. Remove paragraphs (h)(4) through (7);

■ c. Redesignate paragraphs (h)(8) through (22) as paragraphs (h)(4) through (18); and

■ d. Redesignate paragraphs (h)(26) and (27) as paragraphs (h)(19) and (20).

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(51) quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC)	(7222)
(52) quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	(7225)
(53) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA)	(7012)
(54) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA)	(7035)

* * * * *

Dated: August 30, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–21345 Filed 9–2–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0241]

RIN 1625–AA00

Safety Zone; Swim Around Charleston; Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary moving safety zone during the Swim Around Charleston, a swimming race occurring on the Wando River, the Cooper River, Charleston Harbor, and the Ashley River, in Charleston, South Carolina on September 25, 2016. The temporary safety zone is necessary for the safety of the swimmers, participant vessels, spectators, and the general public during the event. The temporary safety zone will restrict vessel traffic in portions of the Charleston Harbor and surrounding rivers. Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Charleston or a designated representative.

DATES: This rule is effective on September 25, 2016 from 8:45 a.m. until 3:45 p.m.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* type USCG–2016–0241 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant John Downing, Sector Charleston Office of Waterways Management, Coast Guard; telephone (843) 740–3184, email *John.Z.Downing@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

On March 17, 2016, Kathleen Wilson notified the Coast Guard that she will be sponsoring the Swim Around Charleston from 9 a.m. to 3:30 p.m. on September 25, 2016. In response, on June 6, 2016, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone, Swim Around Charleston; Charleston, SC. There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this special local regulation. During the comment period that ended July 7, 2016, we received no comments.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable due to the date of the event. The Coast Guard did not receive any adverse comments during the period outlined in the NPRM with regard to this rule.

III. Legal Authority and Need for Rule

The legal basis for this rule is the Coast Guard's Authority to establish regulated navigation areas and other limited access areas: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; and Department of Homeland Security Delegation No. 0170.1.

The purpose of the rule is to ensure the safety of the swimmers, participant vessels, spectators, and the general public life during the Swim Around Charleston.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published June 6, 2016. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from 8:45 a.m. to 3:45 p.m. on September 25, 2016. The safety zone will cover a portion of the waters of the Wando River, Cooper River, Charleston Harbor, and Ashley River, in Charleston, South Carolina. Approximately 120 swimmers are anticipated to participate in the race. Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at (843) 740–7050, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative. The Coast Guard will provide notice of the safety zone by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and executive orders, and we discuss First Amendment rights of protesters.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

The economic impact of this rule is not significant for the following reasons: (1) The temporary safety zone will be enforced for a total of seven hours; (2) the safety zone will move with the participant vessels so that once the swimmers clear a portion of the waterway, the safety zone will no longer be enforced in that portion of the waterway; (3) although persons and vessels may not enter, transit through, anchor in, or remain within the safety zone without authorization from the Captain of the Port Charleston or a designated representative; they may operate in the surrounding area during the enforcement period; (4) persons and vessels may still enter, transit through, anchor in, or remain within the safety zone if authorized by the Captain of the Port Charleston or a designated representative; and (5) the Coast Guard will provide advance notification of the safety zone to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons discussed in the Regulatory Planning and Review section above, this rule will not have a significant economic impact on a substantial number of small entities.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist and a Categorical Exclusion Determination was completed for 2016. The environmental analysis checklist and Categorical Exclusion Determination are available in the docket folder where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 160.5; and Department of Homeland Security Delegation No. 0170.1.

■ 2 . Add § 165.T07–0241 to read as follows:

§ 165.T07–0241 Safety Zone; Swim Around Charleston, Charleston, SC.

(a) *Regulated area.* The following regulated area is a moving safety zone: All waters within a 50-yard radius in front of the lead safety vessel preceding the first race participants, 50 yards behind the safety vessel trailing the last race participants, and at all times extend 100 yards on either side of safety vessels. The Swim Around Charleston swimming race consists of a 12 mile course that starts at Remley Point on the Wando River in approximate position 32°48′49″ N., 79°54′27″ W., crosses the main shipping channel of Charleston Harbor, and finishes at the General William B. Westmoreland Bridge on the Ashley River in approximate position 32°50′14″ N., 80°01′23″ W. All coordinates are North American Datum 1983.

(b) *Definition.* The term "designated representative" means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Charleston in the enforcement of the regulated areas.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Charleston or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at (843) 740–7050, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port Charleston or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative.

(3) The Coast Guard will provide notice of the regulated area by Marine Safety Information Bulletins, Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Effective date.* This rule will is effective on September 25, 2016 and will be enforced from 8:45 a.m. until 3:45 p.m.

B.D. Falk,

Commander, U.S. Coast Guard, Acting Captain of the Port Charleston.

[FR Doc. 2016–21272 Filed 9–2–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[EPA–HQ–OAR–2012–0918; FRL–9951–91–OAR]

Air Quality Designations for the 2012 Primary Annual Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS) for Areas in Georgia and Florida

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is establishing air quality designations in the United States (U.S.) for the 2012 primary annual fine particle ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS) for three areas in Georgia and 62 counties in Florida. When the EPA designated the majority of areas in the country in December 2014, and March 2015, the EPA deferred initial area designations for several locations, including these areas, because the EPA could not determine using available data whether the areas were meeting or not meeting the NAAQS, but we believed that forthcoming data in 2015 would allow the EPA to make that determination. Georgia and Florida have recently submitted complete, quality-assured, and certified air quality monitoring data for 2015 for the areas identified in this notice, and based on these data, the EPA is designating these areas as unclassifiable/attainment for the 2012 primary annual $PM_{2.5}$ NAAQS.

DATES: This final rule is effective on October 6, 2016.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2012–0918. All documents in the docket are listed in the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov.*

In addition, the EPA has established a Web site for the rulemakings to initially designate areas for the 2012 primary annual $PM_{2.5}$ NAAQS at: *https://www3.epa.gov/pmdesignations/2012standards/index.htm.* This Web site includes the EPA's final area designations for the $PM_{2.5}$ NAAQS, as well as state and tribal initial recommendation letters, the EPA's modification letters, technical support documents, responses to comments and other related technical information.

FOR FURTHER INFORMATION CONTACT: For general questions concerning this action, please contact Carla Oldham, U.S. EPA, Office of Air Quality Planning and Standards, Air Quality Planning Division, C539–04, Research Triangle Park, North Carolina 27711, telephone (919) 541–3347, email at *oldham.carla@epa.gov.* The Region 4 contact is Madolyn Sanchez, U.S. EPA, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960, telephone (404) 562–9644, email at *sanchez.madolyn@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 14, 2012, the EPA promulgated a revised primary annual $PM_{2.5}$ NAAQS to provide increased protection of public health from fine particle pollution (78 FR 3086; January 15, 2013). In that action, the EPA strengthened the primary annual $PM_{2.5}$ standard from 15.0 micrograms per cubic meter ($\mu g/m^3$) to 12.0 $\mu g/m^3$, which is attained when the 3-year average of the annual arithmetic means does not exceed 12.0 $\mu g/m^3$.

Section 107(d) of the Clean Air Act (CAA), 42 U.S.C. 7407(d), governs the process for initial area designations after the EPA establishes a new or revised NAAQS. Under CAA section 107(d), each governor is required to, and each tribal leader may, if they so choose, recommend air quality designations, including the appropriate boundaries for "nonattainment" areas, to the EPA by a date which cannot be later than 1 year after the promulgation of a new or revised NAAQS. The EPA considers these recommendations as part of its duty to promulgate the area designations and boundaries for the new or revised NAAQS. If, after careful consideration of these recommendations, the EPA believes that it is necessary to modify a state's recommendation and intends to promulgate a designation different from a state's recommendation, the EPA must notify the state at least 120 days prior to promulgating the final designation and the EPA must provide the state an opportunity to demonstrate why any proposed modification is inappropriate. These modifications may relate either to an area's designation or boundaries.

On December 18, 2014, the Administrator of the EPA signed a final action promulgating initial designations for the 2012 $PM_{2.5}$ NAAQS for the majority of the U.S., including areas of Indian country (80 FR 2206 FR; January 15, 2015). That action designated 14 areas in six states, including two multi-state areas, as nonattainment for the 2012 $PM_{2.5}$ NAAQS. The EPA also designated three areas, including the entire state of Illinois, as "unclassifiable" because the ambient air quality monitoring sites in these areas lacked complete data for the relevant period from 2011–2013. In the absence of complete monitoring data, the EPA could not determine, based on available information, whether these areas meet or do not meet the NAAQS, and also could not determine whether these areas contribute to a nearby violation. Consistent with the EPA's "Policy for Establishing Separate Air Quality Designations for Areas of Indian Country" (December 20, 2011), the EPA designated the lands of the Pechanga Band of Luiseño Mission Indians in Southern California as an unclassifiable/attainment area separate from its adjacent/surrounding state areas. Except for the 10 areas discussed in the next paragraph, the EPA designated all the remaining state areas and areas of Indian country as unclassifiable/attainment.

The EPA deferred initial area designations for 10 areas where available data, including air quality monitoring data, were insufficient to determine whether the areas met or did not meet the NAAQS, but where forthcoming data were likely to result in complete and valid air quality data sufficient to determine whether these areas meet the NAAQS. Accordingly, the EPA stated that it would use the additional time available as provided under section 107(d)(1)(B) of the CAA to assess relevant information and subsequently promulgate initial designations for the identified areas through a separate rulemaking action or actions. The 10 deferred areas included: Eight areas in the state of Georgia, including two neighboring counties in the bordering states of Alabama and South Carolina; the entire state of Tennessee, excluding three counties in the Chattanooga area; the entire state of Florida; and areas of Indian country located in these areas.

In the action published on January 15, 2015, the EPA also described a process by which we would evaluate any complete, quality-assured, certified air quality monitoring data from 2014 that a state submitted for consideration before February 27, 2015 (80 FR 2209). The EPA stated that it would evaluate whether, with the inclusion of certified 2014 data, the 3-year design value for 2012–2014 suggests that a change in the initial designation would be appropriate for an area. If the EPA agreed that a change in the initial designation would be appropriate, the EPA would withdraw the designation announced in the January 15, 2015, action for such area before the effective date and issue another designation reflecting the inclusion of 2014 data (80 FR 2209).

In the follow-up designation action, published on April 15, 2015 (80 FR 18535), the EPA designated five areas in the state of Georgia, including two neighboring counties in the bordering states of Alabama and South Carolina, that were initially deferred in the EPA's January 15, 2015, rulemaking. In the same action, the EPA changed the designation of one area in Ohio, two areas in Pennsylvania, one area shared between Indiana and Kentucky, and one area shared between Kentucky and Ohio. Following that action, designations remained deferred for three areas (covering 14 counties) in Georgia, the entire state of Tennessee (covering 92 counties, excluding three counties in the Chattanooga area), the entire state of Florida (covering 67 counties), and areas of Indian country located in those areas.

II. Purpose and Designation Decisions Based on 2013–2015 Data

The purpose of this action is to announce and promulgate initial area designations of unclassifiable/attainment for the 2012 $PM_{2.5}$ NAAQS for three areas in Georgia,[1] 62 counties in Florida, and Indian country located at least partially in these areas. All of these areas were initially deferred in the EPA's January 15, 2015, rulemaking.[2] Since then, the states of Georgia and Florida submitted to the EPA complete, quality-assured, and certified air quality monitoring data from 2013–2015 for these deferred areas. These data provide the EPA with sufficient information to promulgate initial designations for the three areas in Georgia, 62 counties in Florida, and the associated areas of Indian country at issue in this action. Air quality data collected and submitted to the EPA for 2013–2015 for these areas indicate that the areas are attaining the 2012 $PM_{2.5}$ NAAQS and are not causing or contributing to a violation of the NAAQS in a nearby area. Therefore, the EPA is designating the three areas in Georgia as unclassifiable/attainment. Also, consistent with the EPA's practice in prior rounds of initial area designations for the 2012 $PM_{2.5}$ NAAQS, EPA is designating 62 counties in Florida as unclassifiable/attainment.[3] Areas of Indian country located in these areas are also being designated as unclassifiable/attainment. These designations are consistent with Georgia's and Florida's recommended area designations and boundaries for these areas for the 2012 $PM_{2.5}$ standard. The tables at the end of this final rule (amendments to 40 CFR 81.310—Florida and 40 CFR 81.311—Georgia) list all areas for which the EPA has promulgated an initial designation in each of these two states. Areas of Indian country located in the listed areas are included in the designated area.

III. Environmental Justice Considerations

The CAA requires the EPA to determine through a designation process whether an area meets or does not meet any new or revised national primary or secondary ambient air quality standard. This action includes initial designation determinations for several areas of the U.S. for the 2012 annual $PM_{2.5}$ NAAQS. Area designations ensure that the public is properly informed about the air quality in an area and that, in locations where air quality does not meet the NAAQS, the relevant state authorities are required to initiate appropriate air quality management actions under the CAA to ensure that all those residing, working, attending school or otherwise present in those areas are protected, regardless of minority and economic status.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is exempt from review by the Office of Management and Budget because it responds to the CAA requirement to promulgate air quality designations after promulgation of a new or revised NAAQS.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. This action fulfills the non-discretionary duty for the EPA to promulgate air quality designations after promulgation of a new or revised NAAQS and does not contain any information collection activities.

C. Regulatory Flexibility Act (RFA)

This designation action under CAA 107(d) is not subject to the RFA. The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. Section 107(d)(2)(B) of the CAA explicitly provides that designations are exempt from the notice and comment provisions of the APA. In addition, designations under section 107(d) are not among the list of actions that are subject to the notice and comment procedures of CAA section 307(d).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538 and does not significantly or uniquely affect small governments. The action implements mandates specifically and explicitly set forth in the CAA for the 2012 $PM_{2.5}$ NAAQS (40 CFR 50.18). The CAA establishes the process whereby states take primary responsibility for developing plans to meet the 2012 $PM_{2.5}$ NAAQS.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have a substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

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[1] The areas in Georgia are Albany (Dougherty County); Atlanta (Bartow, Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Forsyth, Fulton, Gwinnett, Henry, and Paulding Counties); and Brunswick (Glynn County).

[2] *See* also the technical support documents for the deferred Georgia and Florida areas in the rulemaking docket, documents numbered EPA–HQ–OAR–2012–0918–0324 and EPA–HQ–OAR–2012–0918–0156 (Georgia); and EPA–HQ–OAR–2012–0918–0323 and EPA–HQ–2012–0918–0332 (Florida).

[3] The EPA has used a weight-of-evidence evaluation to determine an appropriate designation for counties that are adjacent to areas that remain undesignated. *See* Docket No. EPA–HQ–OAR–2012–0918–0324, Georgia Deferred Area Memorandum, discussing certain types of counties "most likely to contribute to a violation of the NAAQS".

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action has tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. Areas of Indian country are being designated unclassifiable/attainment as part of this action.

The EPA offered consultation to tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process to designate areas for the 2012 $PM_{2.5}$ NAAQS to permit them to have meaningful and timely input. In letters dated May 29, 2014, the EPA encouraged tribes to participate in the designations process, request consultation, and submit recommendations. The EPA again offered the opportunity for consultation in letters sent on August 19, 2014. The Seminole Tribe of Florida, which has areas of Indian country affected by this designation action, did not request consultation, nor did they provide a recommendation for designations. Therefore, the EPA did not initiate the consultation process with the tribe for this designation action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 as applying to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on any population, including any minority, low-income or indigenous populations because it does not affect the level of protection provided to human health or the environment. The results of this evaluation of environmental justice considerations is contained in Section III of this preamble titled, "Environmental Justice Considerations."

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the U.S. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

L. Judicial Review

Section 307(b)(1) of the CAA indicates which Federal Courts of Appeal have venue for petitions of review of final actions by the EPA. This section provides, in part, that petitions for review must be filed in the Court of Appeals for the District of Columbia Circuit: (i) When the agency action consists of "nationally applicable regulations promulgated, or final actions taken by the Administrator," or (ii) when such action is locally or regionally applicable, if "such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination."

This final action designating areas across the U.S. for the 2012 annual $PM_{2.5}$ NAAQS is "nationally applicable" within the meaning of CAA section 307(b)(1). At the core of this final action is the EPA's interpretations of the definitions of nonattainment, attainment and unclassifiable under section 107(d)(1) of the CAA, and its application of those interpretations to areas across the country. For the same reasons, the Administrator is also determining that the final designations are of nationwide scope and effect for the purposes of CAA section 307(b)(1). This is particularly appropriate because, in the report on the 1977 Amendments that revised section 307(b)(1) of the CAA, Congress noted that the Administrator's determination that an action is of "nationwide scope or effect" would be appropriate for any action that has a scope or effect beyond a single judicial circuit. H.R. Rep. No. 95–294 at 323, 324, *reprinted* in 1977 U.S.C.C.A.N. 1402–03. Here, the scope and effect of this final action extends to numerous judicial circuits since the designations apply to areas across the country. In these circumstances, CAA section 307(b)(1) and its legislative history calls for the Administrator to find the action to be of "nationwide scope or effect" and for venue to be in the D.C. Circuit.

Thus, any petitions for review of final designations must be filed in the Court of Appeals for the District of Columbia Circuit within 60 days from the date final action is published in the **Federal Register**.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: August 30, 2016.

Gina McCarthy,

Administrator.

For the reasons set forth in the preamble, 40 CFR part 81 is amended as follows:

PART 81—DESIGNATIONS OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401, *et. seq.*

Subpart C—Section 107 Attainment Status Designations

■ 2. Section 81.310 is amended by revising the table entitled "Florida—2012 Annual $PM_{2.5}$ NAAQS (Primary)" to read as follows:

§ 81.310 Florida.

* * * * *

FLORIDA—2012 ANNUAL PM$_{2.5}$ NAAQS

[Primary]

Designated area[1]	Designation		Classification	
	Date[2]	Type	Date[2]	Type
Statewide:				
Alachua County.				
Baker County		Unclassifiable/Attainment.		
Bay County		Unclassifiable/Attainment.		
Bradford County		Unclassifiable/Attainment.		
Brevard County		Unclassifiable/Attainment.		
Broward County.				
Calhoun County		Unclassifiable/Attainment.		
Charlotte County		Unclassifiable/Attainment.		
Citrus County		Unclassifiable/Attainment.		
Clay County		Unclassifiable/Attainment.		
Collier County		Unclassifiable/Attainment.		
Columbia County		Unclassifiable/Attainment.		
DeSoto County		Unclassifiable/Attainment.		
Dixie County		Unclassifiable/Attainment.		
Duval County		Unclassifiable/Attainment.		
Escambia County		Unclassifiable/Attainment.		
Flagler County		Unclassifiable/Attainment.		
Franklin County		Unclassifiable/Attainment.		
Gadsden County		Unclassifiable/Attainment.		
Gilchrist County.				
Glades County		Unclassifiable/Attainment.		
Gulf County		Unclassifiable/Attainment.		
Hamilton County		Unclassifiable/Attainment.		
Hardee County		Unclassifiable/Attainment.		
Hendry County[3]		Unclassifiable/Attainment.		
Hernando County		Unclassifiable/Attainment.		
Highlands County		Unclassifiable/Attainment.		
Hillsborough County		Unclassifiable/Attainment.		
Holmes County		Unclassifiable/Attainment.		
Indian River County		Unclassifiable/Attainment.		
Jackson County		Unclassifiable/Attainment.		
Jefferson County		Unclassifiable/Attainment.		
Lafayette County		Unclassifiable/Attainment.		
Lake County		Unclassifiable/Attainment.		
Lee County		Unclassifiable/Attainment.		
Leon County		Unclassifiable/Attainment.		
Levy County		Unclassifiable/Attainment.		
Liberty County		Unclassifiable/Attainment.		
Madison County		Unclassifiable/Attainment.		
Manatee County		Unclassifiable/Attainment.		
Marion County		Unclassifiable/Attainment.		
Martin County		Unclassifiable/Attainment.		
Miami-Dade County.				
Monroe County		Unclassifiable/Attainment.		
Nassau County		Unclassifiable/Attainment.		
Okaloosa County		Unclassifiable/Attainment.		
Okeechobee County		Unclassifiable/Attainment.		
Orange County		Unclassifiable/Attainment.		
Osceola County		Unclassifiable/Attainment.		
Palm Beach County.				
Pasco County		Unclassifiable/Attainment.		
Pinellas County		Unclassifiable/Attainment.		
Polk County		Unclassifiable/Attainment.		
Putnam County		Unclassifiable/Attainment.		
St. Johns County		Unclassifiable/Attainment.		
St. Lucie County		Unclassifiable/Attainment.		
Santa Rosa County		Unclassifiable/Attainment.		
Sarasota County		Unclassifiable/Attainment.		
Seminole County		Unclassifiable/Attainment.		
Sumter County		Unclassifiable/Attainment.		
Suwanee County		Unclassifiable/Attainment.		
Taylor County		Unclassifiable/Attainment.		
Union County		Unclassifiable/Attainment.		
Volusia County		Unclassifiable/Attainment.		
Wakulla County		Unclassifiable/Attainment.		
Walton County		Unclassifiable/Attainment.		
Washington County		Unclassifiable/Attainment.		

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[1] Includes areas of Indian country located in each county or area, except as otherwise specified.

[2] This date is October 6, 2016, unless otherwise noted.

[3] Includes the Seminole Tribe of Florida Big Cypress Indian Reservation in its entirety.

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■ 3. Section 81.311 is amended by revising the table entitled "Georgia—2012 Annual $PM_{2.5}$ NAAQS (Primary)" to read as follows:

§ 81.311 Georgia.

* * * * *

GEORGIA—2012 ANNUAL $PM_{2.5}$ NAAQS

[Primary]

Designated area[1]	Designation		Classification	
	Date[2]	Type	Date[2]	Type
Statewide:				
Appling County		Unclassifiable/Attainment.		
Atkinson County		Unclassifiable/Attainment.		
Bacon County		Unclassifiable/Attainment.		
Baker County		Unclassifiable/Attainment.		
Baldwin County		Unclassifiable/Attainment.		
Banks County		Unclassifiable/Attainment.		
Barrow County		Unclassifiable/Attainment.		
Bartow County	October 6, 2016	Unclassifiable/Attainment.		
Ben Hill County		Unclassifiable/Attainment.		
Berrien County		Unclassifiable/Attainment.		
Bibb County		Unclassifiable/Attainment.		
Bleckley County		Unclassifiable/Attainment.		
Brantley County		Unclassifiable/Attainment.		
Brooks County		Unclassifiable/Attainment.		
Bryan County		Unclassifiable/Attainment.		
Bulloch County		Unclassifiable/Attainment.		
Burke County		Unclassifiable/Attainment.		
Butts County		Unclassifiable/Attainment.		
Calhoun County		Unclassifiable/Attainment.		
Camden County		Unclassifiable/Attainment.		
Candler County		Unclassifiable/Attainment.		
Carroll County		Unclassifiable/Attainment.		
Catoosa County		Unclassifiable/Attainment.		
Charlton County		Unclassifiable/Attainment.		
Chatham County		Unclassifiable/Attainment.		
Chattahoochee County		Unclassifiable/Attainment.		
Chattooga County		Unclassifiable/Attainment.		
Cherokee County	October 6, 2016	Unclassifiable/Attainment.		
Clarke County		Unclassifiable/Attainment.		
Clay County		Unclassifiable/Attainment.		
Clayton County	October 6, 2016	Unclassifiable/Attainment.		
Clinch County		Unclassifiable/Attainment.		
Cobb County	October 6, 2016	Unclassifiable/Attainment.		
Coffee County		Unclassifiable/Attainment.		
Colquitt County		Unclassifiable/Attainment.		
Columbia County		Unclassifiable/Attainment.		
Cook County		Unclassifiable/Attainment.		
Coweta County	October 6, 2016	Unclassifiable/Attainment.		
Crawford County		Unclassifiable/Attainment.		
Crisp County		Unclassifiable/Attainment.		
Dade County		Unclassifiable/Attainment.		
Dawson County		Unclassifiable/Attainment.		
Decatur County		Unclassifiable/Attainment.		
DeKalb County	October 6, 2016	Unclassifiable/Attainment.		
Dodge County		Unclassifiable/Attainment.		
Dooly County		Unclassifiable/Attainment.		
Dougherty County	October 6, 2016	Unclassifiable/Attainment.		
Douglas County	October 6, 2016	Unclassifiable/Attainment.		
Early County		Unclassifiable/Attainment.		
Echols County		Unclassifiable/Attainment.		
Effingham County		Unclassifiable/Attainment.		
Elbert County		Unclassifiable/Attainment.		
Emanuel County		Unclassifiable/Attainment.		
Evans County		Unclassifiable/Attainment.		
Fannin County		Unclassifiable/Attainment.		
Fayette County		Unclassifiable/Attainment.		
Floyd County		Unclassifiable/Attainment.		
Forsyth County	October 6, 2016	Unclassifiable/Attainment.		
Franklin County		Unclassifiable/Attainment.		
Fulton County	October 6, 2016	Unclassifiable/Attainment.		

GEORGIA—2012 ANNUAL $PM_{2.5}$ NAAQS—Continued

[Primary]

Designated area[1]	Designation		Classification	
	Date[2]	Type	Date[2]	Type
Gilmer County		Unclassifiable/Attainment.		
Glascock County		Unclassifiable/Attainment.		
Glynn County	October 6, 2016	Unclassifiable/Attainment.		
Gordon County		Unclassifiable/Attainment.		
Grady County		Unclassifiable/Attainment.		
Greene County				
Gwinnett County	October 6, 2016	Unclassifiable/Attainment.		
Habersham County		Unclassifiable/Attainment.		
Hall County		Unclassifiable/Attainment.		
Hancock County		Unclassifiable/Attainment.		
Haralson County		Unclassifiable/Attainment.		
Harris County		Unclassifiable/Attainment.		
Hart County		Unclassifiable/Attainment.		
Heard County		Unclassifiable/Attainment.		
Henry County	October 6, 2016	Unclassifiable/Attainment.		
Houston County		Unclassifiable/Attainment.		
Irwin County		Unclassifiable/Attainment.		
Jackson County		Unclassifiable/Attainment.		
Jasper County		Unclassifiable/Attainment.		
Jeff Davis County		Unclassifiable/Attainment.		
Jefferson County		Unclassifiable/Attainment.		
Jenkins County		Unclassifiable/Attainment.		
Johnson County		Unclassifiable/Attainment.		
Jones County		Unclassifiable/Attainment.		
Lamar County		Unclassifiable/Attainment.		
Lanier County		Unclassifiable/Attainment.		
Laurens County		Unclassifiable/Attainment.		
Lee County		Unclassifiable/Attainment.		
Liberty County		Unclassifiable/Attainment.		
Lincoln County		Unclassifiable/Attainment.		
Long County		Unclassifiable/Attainment.		
Lowndes County		Unclassifiable/Attainment.		
Lumpkin County		Unclassifiable/Attainment.		
McDuffie County		Unclassifiable/Attainment.		
McIntosh County		Unclassifiable/Attainment.		
Macon County		Unclassifiable/Attainment.		
Madison County		Unclassifiable/Attainment.		
Marion County		Unclassifiable/Attainment.		
Meriwether County		Unclassifiable/Attainment.		
Miller County		Unclassifiable/Attainment.		
Mitchell County		Unclassifiable/Attainment.		
Monroe County		Unclassifiable/Attainment.		
Montgomery County		Unclassifiable/Attainment.		
Morgan County		Unclassifiable/Attainment.		
Murray County		Unclassifiable/Attainment.		
Muscogee County		Unclassifiable/Attainment.		
Newton County		Unclassifiable/Attainment.		
Oconee County		Unclassifiable/Attainment.		
Oglethorpe County		Unclassifiable/Attainment.		
Paulding County	October 6, 2016	Unclassifiable/Attainment.		
Peach County		Unclassifiable/Attainment.		
Pickens County		Unclassifiable/Attainment.		
Pierce County		Unclassifiable/Attainment.		
Pike County		Unclassifiable/Attainment.		
Polk County		Unclassifiable/Attainment.		
Pulaski County		Unclassifiable/Attainment.		
Putnam County		Unclassifiable/Attainment.		
Quitman County		Unclassifiable/Attainment.		
Rabun County		Unclassifiable/Attainment.		
Randolph County		Unclassifiable/Attainment.		
Richmond County		Unclassifiable/Attainment.		
Rockdale County		Unclassifiable/Attainment.		
Schley County		Unclassifiable/Attainment.		
Screven County		Unclassifiable/Attainment.		
Seminole County		Unclassifiable/Attainment.		
Spalding County		Unclassifiable/Attainment.		
Stephens County		Unclassifiable/Attainment.		
Stewart County		Unclassifiable/Attainment.		
Sumter County		Unclassifiable/Attainment.		

GEORGIA—2012 ANNUAL $PM_{2.5}$ NAAQS—Continued

[Primary]

Designated area[1]	Designation		Classification	
	Date[2]	Type	Date[2]	Type
Talbot County		Unclassifiable/Attainment.		
Taliaferro County		Unclassifiable/Attainment.		
Tattnall County		Unclassifiable/Attainment.		
Taylor County		Unclassifiable/Attainment.		
Telfair County		Unclassifiable/Attainment.		
Terrell County		Unclassifiable/Attainment.		
Thomas County		Unclassifiable/Attainment.		
Tift County		Unclassifiable/Attainment.		
Toombs County		Unclassifiable/Attainment.		
Towns County		Unclassifiable/Attainment.		
Treutlen County		Unclassifiable/Attainment.		
Troup County		Unclassifiable/Attainment.		
Turner County		Unclassifiable/Attainment.		
Twiggs County		Unclassifiable/Attainment.		
Union County		Unclassifiable/Attainment.		
Upson County		Unclassifiable/Attainment.		
Walker County		Unclassifiable/Attainment.		
Walton County		Unclassifiable/Attainment.		
Ware County		Unclassifiable/Attainment.		
Warren County		Unclassifiable/Attainment.		
Washington County		Unclassifiable/Attainment.		
Wayne County		Unclassifiable/Attainment.		
Webster County		Unclassifiable/Attainment.		
Wheeler County		Unclassifiable/Attainment.		
White County		Unclassifiable/Attainment.		
Whitfield County		Unclassifiable/Attainment.		
Wilcox County		Unclassifiable/Attainment.		
Wilkes County		Unclassifiable/Attainment.		
Wilkinson County		Unclassifiable/Attainment.		
Worth County		Unclassifiable/Attainment.		

[1] Includes areas of Indian country located in each county or area, except as otherwise specified.

[2] This date is April 15, 2015, unless otherwise noted.

* * * * *

[FR Doc. 2016–21338 Filed 9–2–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150818742–6210–02]

RIN 0648–XE854

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher/Processors Using Trawl Gear in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; modification of a closure.

SUMMARY: NMFS is opening directed fishing for Pacific cod by catcher/processors using trawl gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to fully use the 2016 total allowable catch apportioned to catcher/processors using trawl gear in the Central Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), September 1, 2016, through 2400 hours, A.l.t., December 31, 2016. Comments must be received at the following address no later than 4:30 p.m., A.l.t., September 21, 2016.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2015–0110, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2015-0110,* click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-

Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679. Regulations governing sideboard protections for GOA groundfish fisheries appear at subpart B of 50 CFR part 680.

NMFS closed directed fishing for Pacific cod by catcher/processors using trawl gear in the Central Regulatory Area of the GOA under § 679.20(d)(1)(iii) on January 1, 2016 pursuant to the final 2016 and 2017 harvest specifications for groundfish of the Gulf of Alaska (81 FR 14740, March 18, 2016).

NMFS has determined that as of August 30, 2016, approximately 1,171 metric tons of Pacific cod remain in the 2016 Pacific cod apportionment for catcher/processors using trawl gear in the Central Regulatory Area of the GOA. Therefore, in accordance with § 679.25(a)(1)(i), (a)(2)(i)(C), and (a)(2)(iii)(D), and to fully use the 2016 total allowable catch (TAC) of Pacific cod in the Central Regulatory Area of the GOA, NMFS is terminating the previous closure and is opening directed fishing for Pacific cod by catcher/processors using trawl gear in the Central Regulatory Area of the GOA. The Administrator, Alaska Region, NMFS, (Regional Administrator) considered the following factors in reaching this decision: (1) The current catch of Pacific cod by catcher/processors using trawl gear in the Central Regulatory Area of the GOA and, (2) the harvest capacity and stated intent on future harvesting patterns of vessels in participating in this fishery.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the opening of directed fishing for Pacific cod by catcher/processors using trawl gear in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of August 30, 2016.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Without this inseason adjustment, NMFS could not allow the fishery for Pacific cod by catcher/processors using trawl gear in the Central Regulatory Area of the GOA to be harvested in an expedient manner and in accordance with the regulatory schedule. Under § 679.25(c)(2), interested persons are invited to submit written comments on this action to the above address until September 21, 2016.

This action is required by § 679.25 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 31, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–21316 Filed 8–31–16; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150916863–6211–02]

RIN 0648–XE851

Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pacific Cod in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; reallocation.

SUMMARY: NMFS is reallocating the projected unused amounts of Pacific cod from American Fisheries Act (AFA) trawl catcher/processors (C/Ps) to Amendment 80 C/Ps in the Bering Sea and Aleutian Islands management area. This action is necessary to allow the 2016 total allowable catch of Pacific cod to be harvested.

DATES: Effective August 31, 2016, through 2400 hrs., Alaska local time (A.l.t.), December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the Bering Sea and Aleutian Islands (BSAI) according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2016 Pacific cod total allowable catch (TAC) specified for AFA trawl C/Ps in the BSAI is 5,166 metric tons (mt) as established by the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016). The Regional Administrator has determined that AFA trawl C/Ps will not be able to harvest 500 mt of the remaining 2016 Pacific cod TAC allocated to those vessels under § 679.20(a)(7)(ii)(A)(*7*). Therefore, in accordance with § 679.20(a)(7)(iii)(A) and § 679.20(a)(7)(iii)(B), NMFS reallocates 500 mt of Pacific cod to Amendment 80 C/Ps in the Bering Sea and Aleutian Islands management area.

The harvest specifications for Pacific cod included in the final 2016 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016) are revised as follows: 4,666 mt to AFA trawl C/Ps and 30,597 mt to Amendment 80 C/Ps.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the reallocation of Pacific cod specified from AFA trawl C/Ps to Amendment 80 C/Ps in the Bering Sea and Aleutian Islands management area. Since these fisheries are currently open, it is important to immediately inform the industry as to the revised allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet as well as processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of August 26, 2016.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 31, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–21315 Filed 8–31–16; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 172
Tuesday, September 6, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Part 382

[Docket No. DOT–OST–2015–0246]

RIN 2105–AE12

Nondiscrimination on the Basis of Disability in Air Travel: Negotiated Rulemaking Committee Fifth Meeting

AGENCY: Office of the Secretary, Department of Transportation.

ACTION: Notice of fifth public meeting of advisory committee.

SUMMARY: This notice announces the fifth meeting of the Advisory Committee on Accessible Air Transportation (ACCESS Advisory Committee).

DATES: The fifth meeting of the ACCESS Advisory Committee will be held on September 21–23, from 9:00 a.m. to 5:00 p.m., Eastern Daylight Time.

ADDRESSES: The meeting will be held at the Ritz Carlton, Pentagon City, 1250 Hayes Street, Arlington, VA 22202. Attendance is open to the public up to the room's capacity of 150 attendees. Since space is limited, any member of the general public who plans to attend this meeting must notify the registration contact identified below no later than September 14, 2016.

FOR FURTHER INFORMATION CONTACT: To register to attend the meeting, please contact Kyle Ilgenfritz (*kilgenfritz@linkvisum.com;* 703–442–4575 extension 128). For other information, please contact Livaughn Chapman or Vinh Nguyen, Office of the Aviation Enforcement and Proceedings, U.S. Department of Transportation, by email at *livaughn.chapman@dot.gov* or *vinh.nguyen@dot.gov* or by telephone at 202–366–9342.

SUPPLEMENTARY INFORMATION:

I. Fifth Public Meeting of the ACCESS Committee

The fifth meeting of the ACCESS Advisory Committee will be held on September 21–23, 2016, from 9:00 a.m. to 5:00 p.m., Eastern Daylight Time. The meeting will be held at the Ritz Carlton, Pentagon City, 1250 Hayes Street, Arlington, VA 22202. At the meeting, the ACCESS Advisory Committee will continue to address whether to require accessible inflight entertainment (IFE) and strengthen accessibility requirements for other in-flight communications, whether to require an accessible lavatory on new single-aisle aircraft over a certain size, and whether to amend the definition of "service animals" that may accompany passengers with a disability on a flight. We expect to negotiate on proposals to amend the Department's disability regulation regarding one or more of these issues. Prior to the meeting, the agenda will be available on the ACCESS Advisory Committee's Web site, *www.transportation.gov/access-advisory-committee.* Information on how to access advisory committee documents via the FDMC is contained in Section III, below.

The meeting will be open to the public. Attendance will be limited by the size of the meeting room (maximum 150 attendees). Because space is limited, we ask that any member of the public who plans to attend the meeting notify the registration contact, Kyle Ilgenfritz (*kilgenfritz@linkvisum.com;* 703–442–4575 extension 128) at Linkvisum, no later than September 14, 2016. At the discretion of the facilitator and the Committee and time permitting, members of the public are invited to contribute to the discussion and provide oral comments.

II. Submitting Written Comments

Members of the public may submit written comments on the topics to be considered during the meeting by September 15, 2016, to FDMC, Docket Number DOT–OST–2015–0246. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. DOT recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that DOT can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* put the docket number, DOT–OST–2015–0246, in the keyword box, and click "Search." When the new screen appears, click on the "Comment Now!" button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing.

III. Viewing Comments and Documents

To view comments and any documents mentioned in this preamble as being available in the docket, go to *www.regulations.gov.* Enter the docket number, DOT–OST–2015–0246, in the keyword box, and click "Search." Next, click the link to "Open Docket Folder" and choose the document to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., E.T., Monday through Friday, except Federal holidays.

IV. ACCESS Advisory Committee Charter

The ACCESS Advisory Committee is established by charter in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2. Secretary of Transportation Anthony Foxx approved the ACCESS Advisory Committee charter on April 6, 2016. The committee's charter sets forth policies for the operation of the advisory committee and is available on the Department's Web site at *www.transportation.gov/office-general-counsel/negotiated-regulations/charter.*

V. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

VI. Future Committee Meeting

DOT anticipates that the ACCESS Advisory Committee will have one additional three-day meeting in

Washington, DC. The sixth and final meeting is tentatively scheduled for October 12–14. Notices of all future meetings will be published in the **Federal Register** at least 15 calendar days prior to each meeting.

Notice of this meeting is being provided in accordance with the Federal Advisory Committee Act and the General Services Administration regulations covering management of Federal advisory committees. *See* 41 CFR part 102–3. Issued under the authority of delegation in 49 CFR 1.27(n).

Dated: August 29, 2016.

Molly J. Moran,

Acting General Counsel.

[FR Doc. 2016–21357 Filed 9–2–16; 8:45 am]

BILLING CODE 4910–9X–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

[Docket No. CPSC–2016–0020]

Statement of Policy on the Commission's Interpretation of Intent To Produce Audible Effects Within the Meaning of the Commission's Fireworks Regulations Under the Federal Hazardous Substances Act

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Proposed interpretive rule.

SUMMARY: The Consumer Product Safety Commission (CPSC) has approved a Proposed Statement of Policy regarding the Commission's interpretation of the phrase "intended to produce audible effects" that appears in the Commission's fireworks regulations.

DATES: Submit comments by October 6, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2016–0020 by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov.* Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written comments by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing by mail/hand delivery/courier.

FOR FURTHER INFORMATION CONTACT: DeWane Ray, Deputy Executive Director for Safety Operations, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301)–504–7547; email: *jray@cpsc.gov.*

SUPPLEMENTARY INFORMATION: Under the Federal Hazardous Substances Act (FHSA),[1] the Consumer Product Safety Commission (CPSC or Commission) has banned all "[f]ireworks devices intended to produce audible effects . . . if the audible effect is produced by a charge of more than 2 grains of pyrotechnic composition."[2] Pursuant to staff's Consumer Fireworks Testing Manual (Manual), Commission staff determine whether a fireworks device was intended to produce an audible effect by evaluating the relative intensity of the sound produced by such device (the Sound Test).

Through this publication, the Commission proposes to interpret the "audible effects" provision such that staff will consider the presence of metallic powder less than 100 mesh in particle size within the burst (or break) charge of a fireworks device to mean the device is intended to produce an audible effect, consistent with the American Pyrotechnic Association Standard 87–1 definition.

The Commission notes that this interpretation is not a binding rule and would not change any person's rights, duties, or obligations under the FHSA or any other Act administered by the Commission. The Commission invites comment on this proposed interpretation.

A. Background

The FHSA empowers the Consumer Product Safety Commission (CPSC or Commission) to, "by regulation[,] declare to be a hazardous substance . . . any substance or mixture of substances"[3] which the Commission finds meets a series of statutory requirements. Under the FHSA, the Commission prohibits, as banned hazardous substances, the introduction into interstate commerce of all

> Fireworks devices intended to produce audible effects (including but not limited to cherry bombs, M–80 salutes, silver salutes, and other large firecrackers, aerial bombs, and other fireworks designed to produce audible effects, and including kits and components intended to produce such fireworks) if the audible effect is produced by a charge of more than 2 grains of pyrotechnic composition.[4]

The goal of this ban was to remove from consumer use the kinds of devices that had, as noted in the 1970 Food and Drug Administration (FDA) rulemaking that imposed the ban, "caused eight fatalities (six were teenage or younger) and a large number of serious injuries ranging from puncture wounds to broken bones and shattered hands."[5]

The Commission's rules do not further define or describe "devices intended to produce audible effects," nor do they define how the Commission will determine whether a product falls under this category. The Manual directs Commission staff to evaluate the relative intensity of any sound produced by a firework device to determine whether such sound is an intended effect or merely incidental to the operation of the device. Any device in the former category must comply with the two grain limitation stated in the regulation.

Since the adoption of the Sound Test, there have been many developments in the fireworks market, including the use of fine-mesh metallic fuels to intensify device operation. Voluntary standards bodies, including the APA, have addressed the use of metallic fuels directly.[6]

Under the APA standard, "any burst [or break] charge containing metallic powder (such as magnalium or aluminum) less than 100 mesh in particle size, is considered to be intended to produce an audible effect, and is limited to 130 mg [the equivalent of two grains] in [consumer] fireworks."[7] This provides a bright-line standard with a highly reproducible measure.

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[1] Pub. L. 86–613, 74 Stat. 372 (July 12, 1960) (codified as amended at 15 U.S.C. 1261–78).

[2] 16 CFR 1500.17(a)(3).

[3] 15 U.S.C. 1262(a)(1).

[4] 16 CFR 1500.17(a)(3). This rule provides an exception for devices intended and sold for bona fide agricultural use. *Id.* at § 1500.17(a)(3)(i)–(ii).

[5] Fireworks Devices, 35 FR 7415 (May 13, 1970).

[6] Amer. Pyrotechnics Assoc., *APA Standard 87–1: Standard for Construction and Approval for Transportation of Fireworks, Novelties, and Theatrical Pyrotechnics* § 2.5 (2001).

[7] *Id.*

Aside from the clarity of its use as an enforcement tool, the APA standard is also familiar to industry. Not only does it reflect the work of a voluntary standard development organization in which industry members participated, it has been incorporated by reference into the Department of Transportation's regulations for the shipment of fireworks.[8] Under this interpretation, CPSC will be testing fireworks devices in line with the APA standard when determining which devices are intended to produce an audible effect.

B. Interpretive Rule

For the foregoing reasons, the Commission proposes to interpret the phrase "Fireworks devices intended to produce audible effects" in a manner consistent with the APA voluntary standard and DOT regulations. Under this interpretation, the Commission will consider the presence in the burst (or break) charge of a fireworks device of metallic powder less than 100 mesh in particle size to mean that the device is intended to produce an audible effect. Likewise, if the device lacks such metallic powder, staff will consider it as not intended to produce an audible effect. This change, as noted above, will not alter the rule or any party's obligations under it in any way, but it will allow the Commission to enforce that rule more efficiently.

C. Request for Comment

The Commission requests comments on all aspects of the proposed interpretation. In particular, given the handmade nature of these products, the Commission requests comments on whether there should be an allowance for contamination at a level that would not pose an injury hazard to fireworks users or bystanders. We seek comments to determine whether we can exercise some flexibility in enforcement. We would not be setting an enforceable contamination allowance but, in an enforcement proceeding, we may consider allowing some contamination if we receive information supporting the position that inadvertent low level contamination by these metals can occur in the manufacturing process.

If so, please provide the CPSC information and data regarding what an appropriate allowance should be.

Dated: August 26, 2016.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2016–21014 Filed 9–2–16; 8:45 am]

BILLING CODE 6355–01–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 4

RIN 3038–AE47

Commodity Pool Operator Annual Report

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: On August 5, 2016, the Commodity Futures Trading Commission (Commission or CFTC) published in the **Federal Register** a notice of proposed rulemaking (Proposal) to amend certain of its regulations applicable to the Annual Report that each person registered or required to be registered as a commodity pool operator (CPO) must distribute for each commodity pool that it operates. As is explained below, the Commission is extending for two weeks the comment period for the Proposal.

DATES: The comment period for the Proposal published on August 5, 2016, at 81 FR 51828, is extended until September 20, 2016.

ADDRESSES: You may submit comments, identified by RIN 3038–AE47 and "Commodity Pool Operator Annual Report," by any of the following methods:

- *CFTC Web site: http://comments.cftc.gov.* Follow the instructions for submitting comments through the Comments Online process on the Web site.
- *Mail:* Send to Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail, above.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Please submit your comments using only one of these methods.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that may be exempt from disclosure under the Freedom of Information Act (FOIA), a petition for confidential treatment of the exempt information may be submitted according to the procedures established in Commission Regulation 145.9.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse, or remove any or all of a submission from *www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the FOIA.

FOR FURTHER INFORMATION CONTACT: Christopher W. Cummings, Special Counsel, 202–418–5445, *ccummings@cftc.gov* or Barbara S. Gold, Associate Director, 202–418–5441, *bgold@cftc.gov,* Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION: The Proposal concerns certain provisions of the Annual Report that registered CPOs are required to distribute and submit under Regulation 4.22. Among other things, it would amend these provisions: To permit the use of additional alternative generally accepted accounting principles, standards or practices; to provide for an exemption from the Annual Report audit requirement where the first fiscal year of a pool consists of a period of three months or less from the date of formation of the pool; and to clarify that a CPO must distribute and submit an audited Annual Report at least once during the life of the pool. The comment period for the Proposal is due to expire on September 6, 2016.

By letter dated August 26, 2016, the Managed Funds Association (MFA), a membership organization representing many persons who would be affected by the Proposal, requested a two-week extension of the comment period for the Proposal, such that, as extended, the comment period would expire on September 20, 2016. In support of its request, MFA explained that it is drafting comments in response to the

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[8] 49 CFR 173.65.

[1] 17 CFR 145.9 (2016). The Commission's regulations are found at 17 CFR Ch. I (2016). They are accessible through the Commission's Web site.

Commission's request for comments on the Proposal and, in this regard, is seeking to provide comments representative of the views of its membership. MFA further explained that it is finding it challenging to ensure that its members have adequate time to review comments for submission by September 6, 2016, in light of previously scheduled family-related commitments which find them out-of-office during the last two weeks of August.

In light of the foregoing, and in response to the MFA request, by this **Federal Register** release the Commission is extending the comment period for the Proposal for two weeks, until September 20, 2016.

Issued in Washington, DC, on August 30, 2016, by the Commission.

Christopher J. Kirkpatrick,

Secretary of the Commission.

Appendix to Commodity Pool Operator Annual Report—Commission Voting Summary

On this matter, Chairman Massad and Commissioners Bowen and Giancarlo voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2016–21153 Filed 9–2–16; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2016–0500]

RIN 1625—AA08

Special Local Regulation; Little Annemessex River and Somers Cove, Crisfield, MD

AGENCY: Coast Guard, DHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Coast Guard is withdrawing its proposed rule concerning amendments to the regattas and marine parades regulations. The rulemaking was initiated to establish special local regulations during the swim segment of the "Crisfield CrabMan Triathlon," a marine event to be held on the waters of the Little Annemessex River and Somers Cove in Somerset County at Crisfield, MD on September 17, 2016. The Coast Guard was notified on July 25, 2016 that the event had been cancelled.

DATES: The proposed rule is withdrawn on September 6, 2016.

ADDRESSES: The docket for this withdrawn rulemaking is available for inspection using the Federal eRulemaking Portal at *http://www.regulations.gov* and can be viewed by following that Web site's instructions.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice, call or email Mr. Ronald Houck, Waterways Management Division, U.S. Coast Guard Sector Maryland-National Capital Region; telephone 410–576–2674, email *Ronald.L.Houck@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background

On July 27, 2016, we published a notice of proposed rulemaking entitled "Special Local Regulation; Little Annemessex River and Somers Cove, Crisfield, MD" in the **Federal Register** (81 FR 17774). The rulemaking concerned the Coast Guard's proposal to establish temporary special local regulations on specified waters of Little Annemessex River and Somers Cove at Crisfield, MD, effective from 5:30 a.m. on September 17, 2016 until 10 a.m. on September 18, 2016. The regulated area included all navigable waters of the Little Annemessex River and Somers Cove, from shoreline to shoreline, bounded to the north by a line drawn from the eastern shoreline of Janes Island at latitude 37°58′39″ N., longitude 075°52′05″ W., and thence eastward to the Crisfield City Dock at latitude 37°58′39″ N., longitude 075°51′50″ W., and bounded to the south by a line drawn from Long Point on Janes Island at latitude 37°58′12″ N., longitude 075°52′42″ W., and thence eastward to Hammock Point at latitude 37°57′58″ N., longitude 075°51′58″ W., located at Crisfield, MD. The regulations were needed to temporarily restrict vessel traffic during the event to provide for the safety of participants, spectators and other transiting vessels.

Withdrawal

The Coast Guard is withdrawing this rulemaking because the event has been cancelled.

Authority

We issue this notice of withdrawal under the authority of 33 U.S.C. 1233.

Dated: August 24, 2016.

Lonnie P. Harrison, Jr.,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2016–21173 Filed 9–2–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF EDUCATION

34 CFR Part 200

RIN 1810–AB33

[Docket ID ED–2016–OESE–0056]

Title I—Improving the Academic Achievement of the Disadvantaged—Supplement Not Supplant

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to establish regulations governing programs administered under title I, part A of the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the Every Student Succeeds Act (ESSA). These proposed regulations are needed to implement recent changes made by the ESSA to the supplement not supplant requirement of title I, part A of the ESEA. Unless otherwise specified, references to the ESEA mean the ESEA, as amended by the ESSA.

DATES: We must receive your comments on or before November 7, 2016.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under "How to use *Regulations.gov.*"
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about these proposed regulations, address them to James Butler, U.S. Department of Education, 400 Maryland Avenue SW., Room 3W246, Washington, DC 20202.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: James Butler, U.S. Department of Education, 400 Maryland Avenue SW., Room 3W246, Washington, DC 20202. Telephone: (202) 260–9737 or by email: *james.butler@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of This Regulatory Action: On December 10, 2015, President Barack Obama signed the ESSA into law. The ESSA reauthorizes the ESEA, which provides Federal funds to improve elementary and secondary education in the Nation's public schools. ESSA builds on the ESEA's legacy as a civil rights law and seeks to ensure every child, regardless of race, national origin, socioeconomic status, background, or zip code, receives the support needed to succeed in school.

As the statute affirms, the purpose of title I, part A of the ESEA is to "provide all children significant opportunity to receive a fair, equitable, and high-quality education, and to close educational achievement gaps." [1] The requirement that title I, part A funds supplement State and local funds, and not supplant them, is a longstanding provision of ESEA intended to ensure that Federal funds provide the additional educational resources that students and teachers in high-poverty schools need to succeed. Consequently, if title I schools do not receive their fair share of State and local dollars before title I dollars are added, title I, part A funds do not serve their intended purpose of providing additional educational resources. In this situation, instead of providing the extra, supplemental funding needed to serve disadvantaged students, they simply compensate for shortfalls in the State and local funds that title I schools receive. Failure to ensure compliance with the supplement not supplant provisions in the law hurts students in title I schools, who are among those most in need of additional support. This principle is fundamental to the law and to its legacy as a civil rights law.

Data show that approximately 90 percent of local educational agencies (LEAs) provide each title I school as much per pupil as the average of non-title I schools in the LEA. However, in hundreds of LEAs across the country, title I schools are receiving, on average, hundreds of thousands of dollars less in State and local funding than the average non-Title I school. These are critical funds that could be spent on, for example, wrap-around services, high-quality preschool, access to advanced coursework, or incentive pay for educators who choose to work in high-need schools. The general requirement that title I, part A funds supplement and do not supplant State and local funds has been part of title I, part A of the ESEA since 1970. This requirement in the law is intended to provide disadvantaged students with additional resources over and above what they receive through State and local funding streams for education. The requirement arose from the findings of a landmark report published in 1969 with support from the National Association for the Advancement of Colored People (NAACP) Legal Defense and Education Fund titled: *Title I of ESEA: Is it Helping Poor Children?.*[2] That report revealed case after case of egregious misuses of title I funds by States and LEAs, including one example from Mississippi where a superintendent averred in Federal court that the highest per-pupil expenditure for schools serving black students in the district was about half of the lowest per-pupil expenditure in schools attended primarily by white students. Due in large measure to the findings from this report, the supplement not supplant provisions for title I, part A were added to the law during the 1970 reauthorization of the ESEA. However, in the years subsequent to the inclusion of this critical safeguard, LEAs struggled with ways to demonstrate compliance with the provision in the statute and oftentimes relied on burdensome practices that worked against the intended purpose of title I funding.

The ESSA presents a significant, positive improvement in this respect, as it changed the manner in which an LEA must comply with this requirement. Prior to the passage of the ESSA, the statute lacked a clear standard for how to demonstrate compliance with the supplement not supplant requirement. Most LEAs met the requirement by demonstrating that each cost or service paid for using title I, part A funds was supplemental. This burdensome practice often limited local education officials' ability to spend title I funds in ways that would best meet the needs of low-achieving students. For example, an LEA often pulled students out of their regular classroom to provide remedial services in order to clearly demonstrate that they were supplemental, regardless of whether this was in the best interest of the students receiving those services.

The new ESSA statutory language focuses not on costs and services, but on funds. Specifically, section 1118(b) of the ESEA requires that an LEA "demonstrate that the methodology used to allocate State and local funds to each [title I school] ensures that such school receives all of the State and local funds it would otherwise receive if it were not receiving assistance under [title I]."

Importantly, States and LEAs need not shift resources among schools in order to comply with this provision, but instead may elect to provide additional State and local educational funding to title I schools to ensure compliance with the supplement not supplant provision of the law.

This is the first time that the supplement not supplant requirement contains a statutory directive regarding how an LEA must demonstrate compliance with the requirement. For this reason, the Department proposes these regulations to provide clarity about how LEAs can demonstrate that the distribution of State and local funds satisfies the funds-based compliance test introduced in the law.

At the same time, the ESSA prohibits the Secretary from prescribing the specific methodology an LEA uses to allocate State and local funds to each school, and the proposed regulations would not establish such a specific methodology. Instead, they would clarify that an LEA must publish its methodology for allocating State and local funds and clarify how the LEA can make the demonstration required by this section of the ESEA and ensure that funds under title I, part A are used to supplement, and not supplant, State and local funds, while also providing the flexibility needed to implement the requirement in a meaningful way. The proposed regulations reflect input provided by negotiators during negotiated rulemaking and feedback received from the public subsequent to the final negotiated rulemaking session, while also building upon the non-regulatory guidance the Department issued in 2015 on the supplement not supplant requirement as applied to schoolwide title I, part A programs, which can be accessed at: *http://www2.ed.gov/policy/elsec/guid/eseatitleiswguidance.pdf.*

Summary of the Major Provisions of This Regulatory Action: For the title I, part A program, we propose new regulations governing supplement not supplant that would:

- Restate the general requirement under section 1118(b)(1) that a State educational agency (SEA) or an LEA use title I, part A funds only to supplement, and not supplant, State and local funds.

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[1] Section 1001 of the ESEA.

[2] *http://files.eric.ed.gov/fulltext/ED036600.pdf.*

- Incorporate the requirement under section 1118(b)(2) of the ESEA that an LEA must demonstrate that the methodology used to allocate State and local funds to each title I school ensures that such school receives all of the State and local funds it would otherwise receive if it were not a title I school.
- Clarify that an LEA may demonstrate compliance with the preceding requirement under the ESEA in a number of ways.
- Provide numerous flexibilities to ensure that an LEA can implement the requirement in a way that reflects local needs, circumstances, and decision-making.
- Clarify the implementation timeline for the proposed regulations.

Costs and Benefits: Although the Department estimates approximately 90 percent of LEAs already meet the requirements of this proposed regulation through the special rule, some LEAs would need to increase funding for some title I schools either by increasing total funding or by redirecting funding within the LEA. Given that some LEAs would need to increase funding for some title I schools, this regulation meets the test for economic significance, as explained in the Regulatory Impact Analysis section of this document, which describes costs, transfers, and benefits of the proposed regulations. We further believe that the proposed regulations would provide a significant benefit by promoting transparency in State and local education spending, and by simplifying and clarifying the test for compliance with the supplement not supplant requirement in the ESEA, which is designed to ensure that Federal education funds provided through the title I, part A program meet their statutory purpose. Please refer to the *Regulatory Impact Analysis* section of this document for a more detailed discussion of costs and benefits. Consistent with Executive Order 12866, the Office of Management and Budget has determined that this action is economically significant.

Invitation to Comment: We invite you to submit comments regarding these proposed regulations. To ensure that your comments have maximum effect in developing the final regulations, we urge you to identify clearly the specific section or sections of the proposed regulations that each of your comments addresses and to arrange your comments in the same order as the proposed regulations.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from these proposed regulations. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the Department's programs and activities.

During and after the comment period, you may inspect all public comments about these proposed regulations by accessing *Regulations.gov.* You may also inspect the comments in person in 3W246, 400 Maryland Ave. SW., Washington, DC, between 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays. Please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Particular Issues for Comment: We request comments from the public on any issues related to these proposed regulations. However, we particularly request the public to comment on, and provide additional information regarding, the following issue. Please provide a detailed rationale for your response.

- Whether we should expand the flexibility available to an LEA that chooses to use the special rule, including to expand the categories of expenditures that disproportionately affect the amount of State and local funds allocated on average for non-title I schools, as contemplated in § 200.72(b)(1)(iii)(C).

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for these proposed regulations. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Background

Public Participation

On December 22, 2015, the Department published a request for information in the **Federal Register** soliciting advice and recommendations from the public on the implementation of title I of the ESEA. We received 369 comments. We also held two public meetings with stakeholders—one on January 11, 2016, in Washington, DC and one on January 19, 2016, in Los Angeles, California—at which we heard from over 100 speakers regarding the development of regulations, guidance, and technical assistance related to the implementation of title I. In addition, Department staff have held more than 200 meetings with education stakeholders and leaders across the country to hear about areas of interest and concern regarding implementation of the new law.

Negotiated Rulemaking

Section 1601(b) of the ESEA requires the Secretary, before publishing proposed regulations for programs authorized by title I, part A of the ESEA, to obtain public involvement in the development of the proposed regulations. After obtaining advice and recommendations from individuals and representatives of groups involved in, or affected by, the proposed regulations, the Secretary must subject any proposed regulations related to standards or assessments under section 1111(b)(2) of the ESEA, as well as the requirement under section 1118(b) that funds under part A be used to supplement, and not supplant, State and local funds, to a negotiated rulemaking process.

On February 4, 2016, the Department published a notice in the **Federal Register** (81 FR 5969) announcing our intent to establish a negotiated rulemaking committee to develop proposed regulations to implement certain changes made to the ESEA by the ESSA. We announced our intent to establish a negotiating committee to prepare proposed regulations related to the requirement under section 1118(b) of the ESEA that title I, part A funds be used to supplement, and not supplant, non-Federal funds, specifically:

(i) Regarding the methodology an LEA uses to allocate State and local funds to each title I school to ensure compliance with the supplement not supplant requirement; and

(ii) The timeline for compliance.

The committee met in three sessions to develop proposed regulations, which also included proposals related to assessments under section 1111(b)(2) of the ESEA: Session 1, March 21–23, 2016; session 2, April 6–8, 2016; and session 3, April 18–19, 2016.

The committee included the following members:

Tony Evers and Marcus Cheeks, representing State administrators and State boards of education.

Alvin Wilbanks, Derrick Chau, and Thomas Ahart (alternate), representing local administrators and local boards of education.

Aaron Payment and Leslie Harper (alternate), representing tribal leadership.

Lisa Mack and Rita Pin-Ahrens, representing parents and students, including historically underserved students.

Audrey Jackson, Ryan Ruelas, and Mary Cathryn Ricker (alternate), representing teachers.

Lara Evangelista and Aqueelha James, representing principals.

Eric Parker and Richard Pohlman (alternate), representing other school leaders, including charter school leaders.

Lynn Goss and Regina Goings (alternate), representing paraprofessionals.

Delia Pompa, Ron Hager, Liz King (alternate), and Janel George (alternate), representing the civil rights community, including representatives of students with disabilities, English learners, and other historically underserved students.

Kerri Briggs, representing the business community.

Patrick Rooney and Ary Amerikaner (alternate), representing the U.S. Department of Education.

The committee's protocol provided that it would operate by consensus, which meant unanimous agreement; that is, without dissent by any voting member. During its meetings, the committee reviewed and discussed drafts of proposed regulations. At the final meeting in April 2016, the committee did not reach consensus on the proposed regulations relating to the requirement under section 1118(b) of the ESEA that title I, part A funds be used to supplement, and not supplant, State and local funds.

Because consensus was not reached, the Department may use regulatory language developed during the negotiations as the basis for the proposed regulations, or develop new regulatory language for all or a portion of the proposed regulations; and all parties who participated or were represented in the negotiated rulemaking, as well as all members of the public, may comment freely on the proposed regulations. In addition, as required under section 1601(c)(1) of the ESEA, on August 12, 2016, the Department submitted the proposed regulations to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Education and the Workforce in the House of Representatives for a 15 business-day comment period. The Department will include and seek to address comments received from Congress in the public rulemaking record for these regulations. Further information on the negotiated rulemaking process may be found at: *http://www2.ed.gov/policy/elsec/leg/essa/index.html.*

Proposed Regulations

The Secretary proposes new regulations in 34 CFR part 200 to implement programs under title I, part A of the ESEA. We discuss substantive issues under the sections of the proposed regulations to which they pertain.

Section 200.72 Supplement Not Supplant

Statute: Section 1118(b) of the ESEA requires that an SEA and LEA use the funds that each receives under part A of title I only to supplement, and not supplant, the funds made available from State and local sources for the education of students in title I schools.

According to the statutory language of the ESEA, to meet the supplement not supplant requirement an LEA must demonstrate that the methodology it selects for allocating State and local funds results in each title I school receiving all of the State and local funds that it would otherwise receive if it were not receiving title I funds. The statute also clarifies that an LEA is not required to: (1) Identify that an individual cost or service supported with funds it receives under title I, part A is supplemental; or (2) provide services through a particular instructional method or in a particular instructional setting. Further, the statute specifically prohibits the Department from prescribing the specific methodology that an LEA must use to allocate State and local funds.

Section 1118(b)(5) establishes December 10, 2017, as the deadline by which an LEA must demonstrate to its SEA compliance with the supplement not supplant requirement. Before December 10, 2017, an LEA may continue to use its existing method for complying with the supplement not supplant requirement.

Current Regulations: None.

Proposed Regulations: The proposed regulations would incorporate new statutory provisions and clarify the basic responsibilities an SEA or LEA has in ensuring that the funds received under title I, part A are used only to supplement, and not to supplant, State and local funds that are made available to support the education of students in title I schools.

Proposed § 200.72(a)(1)(i) would incorporate the statutory requirement that an SEA or LEA must use title I, part A funds only to supplement State and local funds that would, in the absence of title I, part A funds, be made available for the education of students in title I schools. Proposed § 200.72(a)(1)(ii) would establish that an SEA or LEA may not use title I, part A funds to supplant State and local funds.

Proposed § 200.72(a)(2)(i) would make clear that an LEA is not required to identify an individual cost or service supported with funds under title I, part A as supplemental, and proposed § 200.72(a)(2)(ii) would clarify that an LEA is not required to use title I, part A funds to provide services through a particular instructional method or in a particular instructional setting.

Proposed § 200.72(b)(1)(i) would clarify that an LEA must demonstrate annually to its SEA that the methodology it uses to allocate State and local funds to each title I school ensures that each title I school receives all of the State and local funds that it would receive if it were a non-title I school. Under the proposed regulations, an SEA must establish the time and form for the annual LEA demonstration. Also, an LEA would need to publish its methodology in a manner easily accessible to the public.

Proposed § 200.72(b)(1)(ii) would clarify that an LEA must allocate almost all State and local education funds to all of its public schools—regardless of title I status—in a way that meets one of the following tests: (A) The actual distribution of funds is based on the characteristics of students in each school, providing more funding for students with characteristics associated with educational disadvantage including students living in poverty, English learners, students with disabilities, and other such subgroups of students chosen by the LEA; (B) the actual distribution of funds is based on a districtwide formula for allocation of personnel and non-personnel resources, provided that the total amount going to each title I school is at least equal to the sum of the amount of personnel costs expected based on the districtwide average salary for each category of school personnel and the average district-wide per pupil expenditure for non-personnel costs; or (C) the distribution of funds through any other approach that meets a funds-based compliance test established by the SEA that is as rigorous as (A) or (B) and is approved through Federal peer review that relies on peers such as professionals with expertise in school finance, State and local education officials, and individuals who represent the interests of special populations of students. An SEA would not be required to establish such a test. Moreover, an LEA would not be required to use the SEA's test if the LEA complies with one of the other two options or the special rule discussed below.

To meet one of these tests, an LEA may create a specific funding methodology to best address its local context and need. Under any methodology, an LEA may exclude certain funding used for districtwide activities, as provided in proposed § 200.72(b)(2)(iv), provided that each title I school receives a share of those activities equal to or greater than the share it would otherwise receive if it were not a title I school. For example, an LEA might exclude State or local funds used for districtwide administrative costs, to implement a districtwide summer school or preschool program, or personnel providing districtwide services such as curriculum development or data analysis.

In addition, proposed § 200.72(b)(1)(iii) establishes a "special rule" that an LEA may use to meet the compliance test, rather than using one of the three options described above. Recent school-level expenditure data from the 2013–2014 school year show that approximately 90 percent of LEAs currently would meet the special rule. However, in approximately 1,500 LEAs, 5,750 title I schools spend significantly less State and local funding than non-title I schools in the same grade span (*e.g.*, high schools or elementary schools) in the same LEA. Each year, these title I schools receive hundreds of thousands of dollars less in State and local funding than their non-title I counterparts in the same LEA—$440,000 per year, on average, or a median of roughly $200,000 per year.[3] These data suggest that in thousands of schools serving high-need students, title I, part A funds are being used, at least in part, to make up for underfunding at the State and local level, rather than providing truly supplemental funds.[4]

Under the "special rule" option, the LEA simply would demonstrate, regardless of the methodology it uses to allocate State and local funds to title I schools, that it spends an amount of State and local funds on a per-pupil basis in each title I school that is equal to or greater than the average per-pupil amount spent in non-title I schools, using data reported under section 1111(h)(1)(C)(x) of the ESEA. The proposed special rule also would allow for de minimis variations in annual expenditures, such that an LEA would be in compliance with the special rule provision if the amount it spends per pupil in each title I school is no more than 5 percent below the average amount it spends per pupil in non-title I schools. In addition, proposed § 200.72(b)(1)(iii)(B) would allow an LEA using the special rule provision to exclude from the calculation of its per-pupil spending funds spent in a school that enrolls fewer than 100 students, while proposed § 200.72(b)(1)(iii)(C) would allow such an LEA to comply using the special rule provision if a non-title I school serving high proportions of students with disabilities, English learners, or students from low-income families has higher per-pupil expenditures due to serving those students and disproportionately affects the average amount of State and local funds spent in non-title I schools in the LEA or grade span.

Proposed § 200.72(b)(2) provides flexibilities that an LEA may use in demonstrating compliance with the ESEA's supplement not supplant requirement. Specifically:

- Proposed § 200.72(b)(2)(i) would establish that an LEA may comply with the supplement not supplant requirement on a districtwide or grade-span basis (*e.g.*, high schools, elementary schools).
- Proposed § 200.72(b)(2)(ii) would exempt an LEA from complying with the supplement not supplant requirement if it serves only a single school or in any grade span in which it serves only a single school.
- Proposed § 200.72(b)(2)(iii) would clarify that, consistent with section 1118(d) of the ESEA, an LEA may exclude from its demonstration of compliance supplemental State and local funds expended in any school—including a non-title I school—for programs that meet the intent and purposes of title I, part A (*e.g.*, a State-funded program providing additional services only for students most at risk of not meeting challenging State academic standards).
- Proposed § 200.72(b)(2)(iv) would allow an LEA that spends State or local funds for certain districtwide activities to exclude those funds from its demonstration of compliance, provided that each title I school receives a share of those activities equal to or greater than it would otherwise receive if it were not a title I school and that the LEA distributes to schools under paragraph (b)(1) almost all of the State and local funds available to it. It would further clarify that districtwide activities may include, for example, districtwide administrative costs, districtwide programs such as summer school or preschool, and personnel providing districtwide services such as curriculum development or data analyses but may not include personnel or non-personnel resources associated with an individual school.

Proposed § 200.72(b)(3)(i) would clarify the timeline for meeting the new compliance test required by the ESEA. By December 10, 2017, an LEA would be required to either (1) demonstrate to its SEA that its current methodology for allocating State and local funds meets the new supplement not supplant requirement, or (2) provide to its SEA a plan describing how it would meet that requirement no later than the 2019–2020 school year.

Proposed § 200.72(b)(3)(ii) would clarify that, during the transition to the new title I, part A supplement not supplant requirement under the ESEA, an LEA would be able to use either (1) the methodology it will use to comply with the new supplement not supplant requirement, or (2) the methodology it used for complying with the requirement as it existed prior to enactment of the ESSA.

Proposed § 200.72(b)(4) would clarify that nothing in the proposed regulation shall be construed to require the forced or involuntary transfer of school personnel. It would further clarify that, consistent with section 1605 of the ESEA, the proposed regulation would not require equalized per-pupil spending for a State, LEA, or school. It would make clear that nothing in the proposed regulations would require an LEA to adopt a specific methodology to allocate State and local funds to comply with the supplement not supplant requirement. Finally, proposed § 200.72(b)(4) would make clear that nothing in the proposed regulations would alter or otherwise affect the rights, remedies, and procedures afforded to school or LEA employees under Federal, State, or local laws (including applicable regulations or court orders) or under the terms of collective bargaining agreements, memoranda of understanding, or other agreements between such employers and their employees.

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[3] These estimates are based on U.S. Department of Education (Department) analyses of data from the 2013–2014 Civil Rights Data Collection, and calculated in a manner consistent with the "special rule" provision of the regulations proposed in this notice. Accordingly, the 90 percent figure includes in the denominator districts to which the supplement not supplant compliance test would not apply (*e.g.*, districts with all title I schools or no title I schools). A public-use version of the collection can be found here.

[4] This practice did not *per se* result in non-compliance with the supplement not supplant requirement in section 1120A(b) of the ESEA, as amended by the No Child Left Behind Act of 2001, which did not contain statutory provisions relating to how LEAs must demonstrate compliance with the supplement not supplant requirement. In the absence of that clarity, the Department relied on a set of presumptions of supplanting for monitoring and enforcement purposes. However, these presumptions are no longer relevant because the new supplement not supplant requirement under section 1118(b) of the ESEA for the first time clarifies that compliance relies on an LEA's methodology for allocating State and local *funds* and discourages the use of past and onerous practices by prohibiting LEAs from being required to demonstrate that an individual cost or service is supplemental.

Reasons: We propose these regulations to implement the changes made by the ESSA to the supplement not supplant requirement of title I, part A of the ESEA. The proposed regulations would ensure that title I funds are used to fulfill their statutory purpose—that is, to "provide all children significant opportunity to receive a fair, equitable, and high-quality education, and to close educational achievement gaps"—instead of making up for inequitable allocations of State and local funding to title I schools. The proposed regulations also would provide LEAs the flexibility necessary to implement this requirement in a manner that accounts for local needs and circumstances while respecting the core purpose of the statute. Finally, the proposed regulations would clarify that previous burdensome compliance tests—related to justifying individual expenditures of title I funds—are no longer required.

While section 1118(b) of the ESEA establishes that, to comply with the supplement not supplant requirement, an LEA must demonstrate that it uses a methodology to allocate State and local funds that ensures that each title I school receives the same amount of those funds as it would if it were not receiving title I funding, the statute does not indicate how an LEA is to make this demonstration. Some stakeholders, including some members of the negotiating committee, expressed an interest in clear requirements so that LEAs know exactly how they are expected to comply, and so that auditors are not forced to make ad hoc decisions on what constitutes an appropriate demonstration of compliance with the statute that could vary significantly from LEA to LEA and potentially have an unfair impact on students, schools, and LEAs. Some stakeholders expressed support for the Department's proposal during the negotiated rulemaking process that would have required that an LEA receiving title I funds demonstrate that each title I school spend at least as much per pupil in State and local funding as the average spent in non-title I schools in the LEA. However, other negotiators expressed strong concern that this may not be the only appropriate test of compliance with the supplement not supplant requirement. Many of those who expressed such concern also expressed support for the examples in the supplement not supplant section of the Department's 2015 non-regulatory guidance on schoolwide title I, part A programs, from which we drew in the development of this proposed rule. Some negotiators also expressed support for using a proposed rule to simply ensure transparency regarding an LEA's methodology for allocating State and local funds. Finally, some negotiators recommended not regulating on this provision of the law at all.

The proposed regulations would require transparency in how an LEA allocates State and local funds, and would provide LEAs with three distinct options to demonstrate compliance with the requirement, including the two options outlined in the 2015 schoolwide program guidance as well as an SEA-developed funds-based compliance test that would be approved through a Federal peer review process. The first two options would allow for the demonstration of compliance through funds-based methodologies that direct resources to all public schools in an LEA on the basis of student characteristics or through the allocation of staffing and supplies. The third option was added in order to maximize flexibility for innovative approaches, consistent with the funds-based requirement established by the ESSA, that ensure LEAs are using title I funds to supplement State and local funds.

The proposed regulations would require that an LEA distribute almost all State and local funds through one of the three methodologies. This recognizes that some portion of State and local funding may not be allocated through general formulas because it is used for districtwide activities under proposed § 200.72(b)(2)(iv).

The proposed regulations would also provide an LEA the choice of complying with the supplement not supplant requirement via a "special rule" instead of one of the three options described above. The special rule builds upon the Department's proposal from negotiated rulemaking. During the negotiated rulemaking process, the negotiators raised important considerations about special circumstances that would require flexibility when implementing the special rule of the proposed regulations. To address these concerns, proposed § 200.72(b)(1)(iii) would:

- Provide that the special rule is met if the amount an LEA spends per pupil in each title I school is no more than 5 percent below the average amount it spends in non-title I schools, which would enable LEAs to develop and implement a methodology consistent with the supplement not supplant requirement while allowing for small and unpredictable shifts in costs from year to year;
- Allow an LEA electing to use the special rule to exclude the costs of educating students in schools that enroll fewer than 100 students. Data collected by the Department indicate that schools that educate between 1 and 49 students spend about 60 percent more per student than the national average, and schools that educate 50 to 99 students spend about 45 percent more than the national average;[5] and
- Provide an opportunity for an LEA to comply with the special rule if the average per-pupil expenditures in non-title I schools is disproportionately impacted by a school serving a high proportion of students with disabilities, English learners, or students from low-income families. This opportunity is designed to ensure that an LEA may continue providing such additional support in a school that serves a disproportionate proportion of these high-need students and is not receiving title I funds.

The negotiators also identified possible complexities in LEA funding systems that merit additional flexibility. Consequently, all of the options provided in proposed § 200.72(b)(1)(ii) as well as the special rule provision in proposed § 200.72(b)(1)(iii) include flexibilities in § 200.72(b)(2) that would:

- Allow an LEA to demonstrate compliance on a districtwide or grade-span basis, because the costs of operating a high school frequently differ from the costs of operating an elementary school;
- Exempt an LEA with a single school or a single school per grade span from the requirement;
- Consistent with section 1118(d) of the ESEA, allow an LEA to exclude supplemental State or local funds spent for programs that are consistent with the intent and purposes of title I, part A (*e.g.,* a State-funded program providing additional services only for students most at risk of not meeting State standards) from its demonstration of compliance with the ESEA's supplement not supplant requirement; and
- Allow an LEA to exclude funds used for districtwide activities from its demonstration of compliance, provided that the LEA ensures that each title I school receives an equal or greater share of those districtwide activities as it would receive if it were a non-title I

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[5] These data are based on Department analyses of data from the 2013–2014 Civil Rights Data Collection.

school and the LEA distributes to schools under paragraph (b)(1) almost all of the State and local funds available to it.

The Department acknowledges that, in some LEAs, compliance with the new supplement not supplant requirement under the ESEA will require shifts in spending and budgeting practices, and that making these shifts may not be possible before December 10, 2017. Therefore, the proposed regulations would allow an LEA unable to comply by December 10, 2017, to provide and implement a plan to come into compliance by the 2019–2020 school year.

Finally, the Department includes four rules of construction. The first would clarify that these regulations should not be construed to require the forced or involuntary transfer of any school personnel. We encourage an LEA to consider all available options to meet the supplement not supplant requirement under the ESEA, including, for example, improving working conditions in high-poverty and hard-to-staff schools to attract the best and best-paid educators, providing additional compensation or some other incentive to educators in high-poverty and hard-to-staff schools, and increasing wrap-around services or other resources in high-poverty and hard-to-staff schools, such as school counselors, school-based health providers, extended learning time, or high-quality preschool opportunities. Whichever strategies an LEA chooses, the Department encourages the LEA to comply with this requirement through increasing funding focused on high-poverty, hard-to-staff schools.

The second rule of construction would clarify that the proposed regulations do not require equalized spending per-pupil for a State, LEA, or school. The proposed regulations contemplate variations in per-pupil spending across schools—for example, an LEA taking advantage of the special rule provision would likely have (1) variation in spending among title I schools, so long as each was above the average per pupil expenditures for non-title I schools, (2) variation in spending among non-title I schools, which would be averaged to determine the average per pupil expenditures in non-title I schools, (3) variation in spending across grade-spans, and (4) higher spending in very small schools that are exempted from the calculations altogether. Similarly, an LEA choosing to use a weighted student funding formula would have variation across schools depending on the characteristics of each school's student population. And an LEA choosing to allocate personnel and non-personnel resources is likely to have wide variation in spending depending upon the specifics of the district's formula (*e.g.,* whether the formula allocates varied numbers of staff per student in elementary schools compared to high schools; whether the formula "counts" students with disabilities as "1.2" students or "1.4" students). The rule of construction would clarify that an LEA is not limited to formulations that would require spending identical sums of money per pupil in each school. The third rule of construction would make clear that nothing in the proposed regulations would require an LEA to adopt a specific methodology to allocate State and local funds to comply with the supplement not supplant requirement in violation of section 1118(b)(4) of the ESEA.

The fourth rule of construction would clarify that nothing in the proposed regulations would alter or otherwise affect the rights, remedies, and procedures afforded to school or LEA employees under Federal, State, or local laws (including applicable regulations or court orders) or under the terms of collective bargaining agreements, memoranda of understanding, or other agreements between such employers and their employees.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Office of Management and Budget must determine whether this regulatory action is "significant" and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an "economically significant" rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed regulatory action is an economically significant regulatory action subject to review by OMB under section 3(f)(1) of Executive Order 12866. This determination is based on the Department's estimate that LEAs currently not able to demonstrate compliance with the supplement not supplant requirements of the proposed rule may have to transfer approximately $800 million in existing State and local education funds to demonstrate such compliance. This potential transfer is deemed an economically significant transfer under section 3(f)(1) of Executive Order 12866.

We have also reviewed these regulations under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include "identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes."

We are issuing these proposed regulations only on a reasoned determination that their benefits would justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that these proposed regulations are consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, we have assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action and have determined that the benefits would justify the costs.

The potential costs associated with the proposed regulations are those resulting from statutory requirements and those we have determined as necessary for administering these programs effectively and efficiently. The proposed regulations would implement new statutory requirements in the ESEA related to demonstrating compliance with the longstanding supplement not supplant requirement. More specifically, under the ESEA, an LEA must "demonstrate that the methodology used to allocate State and local funds for each [title I school] ensures that such school receives all of the State and local funds it would otherwise receive if it were not receiving assistance under [title I, part A]." The proposed regulations would not require a specific methodology for allocating funds, but would require that the methodology selected and used by each LEA results in an actual distribution of funds consistent with the statutory requirement that each school participating in title I, part A receives all of the State and local funds it would otherwise receive if it were not a title I school, while also providing flexibility designed to accommodate local circumstances that might reasonably affect an LEA's ability to meet the supplement not supplant requirement.

The Department estimates that at least 90 percent of LEAs would comply with the proposed regulations without any change in current allocation practices.[6] These LEAs would be able to demonstrate compliance through the special rule option, which allows an LEA to choose any methodology that results in the LEA spending an amount of State and local funds per pupil in each title I school that is equal to or greater than the average amount of State and local funds spent per pupil in non-title I schools, using per-pupil expenditure data they will be required to collect and report under section 1111(h)(1)(C)(x) of the ESEA. In general, the Department believes that the flexibility afforded to LEAs by the proposed regulations in demonstrating compliance with the title I, part A supplement not supplant requirement would minimize the administrative costs and burdens of complying with the proposed regulations. The Department also believes that, once fully implemented, the proposed regulations would be significantly less burdensome and costly in comparison to the requirements of current law, which often involve detailed tracking and documentation of individual education expenditures.

The proposed regulations would not require the expenditure of additional State or local funds in title I schools; rather, an LEA could meet one of the proposed compliance tests through the reallocation of existing State and local resources. For example, the Department estimates that the approximately 1,500 LEAs currently spending, on average, more State and local funds in their non-title I schools than their title I schools would need to transfer approximately $800 million in State and local education funds to their title I schools in order to meet the special rule in the proposed regulations. The average percentage of State and local dollars that would need to be reallocated by affected LEAs is estimated to be 1 percent. We note that the total dollars that would be required to be redistributed under the proposed regulations represent just over one-tenth of one percent of the more than $600 billion that State and local communities spend annually on public elementary and secondary education.

Instead of transferring funds, affected LEAs and the States in which they are located may elect to increase State and local expenditures to meet the supplement not supplant requirement of the proposed regulations. If all affected LEAs do this, the total additional funding required is estimated to be approximately $2.2 billion, or an increment of roughly one-third of one percent over current State and local spending on public elementary and secondary schools. The Department notes that while the proposed regulations would not require the expenditure of additional State or local funds to demonstrate compliance, doing so would ensure additional support for students and teachers in title I schools consistent with the supplement not supplant requirement, while avoiding any reduction in financial support for students and teachers in non-title I schools.

The Department does not have sufficient data to support detailed estimates of the impact of using either the districtwide pupil characteristics formula test or the districtwide personnel and non-personnel resource formula test to demonstrate compliance with the proposed supplement not supplant requirement. However, the Department believes that under either approach, the total amount of existing funds that affected LEAs would have to transfer, or the additional expenditure of State or local funds that would be required, would be similar to the estimates provided for the special rule, based on estimating the differences in funding between each title I school and the districtwide average funding. Similarly, the Department cannot provide an estimate of the impact of any State-determined option for compliance, but also believes that the total amount of existing funds that affected districts would have to transfer, or the additional expenditure of State or local funds that would be required, would be similar under this option, given that any such State-determined option must be "as rigorous" as the other options.

States and LEAs would incur certain administrative costs under the proposed regulations. For example, while it is difficult to predict the number of States that would elect to develop their own, alternative compliance tests, the Department estimates that 15 States would incur additional one-time costs of developing or adopting and submitting an alternative funds-based compliance test for Federal peer review and approval that then could be used by LEAs to demonstrate compliance with the proposed supplement not supplant requirements. The Department further estimates that these 15 States would need, on average, 48 hours to prepare and submit such an alternative funds-based compliance test for peer review. At $40 per hour, the average cost per State would be $1,920, resulting in a total cost across the estimated 15 States of $28,800. We expect that States generally would use Federal education program funds they reserve for State administration under title I, part A to cover these one-time costs.

The Department also estimates that the approximately 1,500 LEAs that we estimate currently would not comply with the special rule in the proposed regulations would need, on average, 24 hours to develop or adopt an alternative funds-based compliance test consistent with one of the options in the proposed regulations. We further estimate that, assuming a $35 hourly cost, these LEAs would spend an average of $840 to develop or adopt a test for demonstrating compliance with the proposed supplement not supplant regulations, for a total estimated cost across 1,500 LEAs of $1,260,000. As under the State example, we anticipate that most LEAs would use a portion of Federal program funds received under title I, part A to pay these one-time development costs.

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[6] These estimates are based on Department analyses of data from the 2013–2014 Civil Rights Data Collection, and are calculated in a manner consistent with the special rule provisions of the regulations proposed in this notice.

The Department also believes that for most LEAs, adjusting allocations of State and local education resources to demonstrate compliance with the proposed regulations generally would not entail significant new administrative burden because such adjustments could be accomplished through their normal annual budget processes. However, we estimate that approximately one third of LEAs that currently would not comply with the proposed special rule would need to transfer more than 1 percent of State and local funds in order to demonstrate compliance with the proposed regulations, and that these 500 LEAs would need to (1) develop multi-year plans for meeting their selected compliance tests and (2) integrate these plans into their annual budget processes. The Department estimates that these 500 LEAs would need, on average, 28 hours at a cost of $35 per hour to develop and integrate these plans into their annual budget processes, for a total estimated cost of $490,000. We note that there is likely substantial variation around the 28-hour average, with some LEAs potentially requiring significantly more time to develop and implement their compliance plans.

The estimated administrative costs of the proposed regulations, which total less than $2 million for States and LEAs, are a small fraction of the more than $15 billion provided by the title I, part A program. Moreover, these costs are outweighed by the fact that for the vast majority of LEAs (*i.e.,* the more than 90 percent of LEAs that are likely to already comply through the special rule), demonstrating compliance with the proposed regulations would be significantly less complex and burdensome than the supplement not supplant requirements of current law, which typically have involved detailed tracking of education expenditures in order to demonstrate that Federal title I funds are not supplanting State or local funds. Thousands of LEAs no longer would incur the annual costs of tracking, reporting, and auditing individual education expenditures that are the predominant practice for complying with supplement not supplant under current law. For all of these reasons, we believe the proposed regulations generally would not impose significant costs on either States or LEAs, and that for the minority of LEAs that do experience additional, mostly one-time implementation costs, such costs would be substantially offset by reduced administrative burdens once the proposed regulations are fully implemented.

Equally important, the proposed regulations would provide a significant benefit for the vast majority of LEAs by simplifying and clarifying the test for compliance with the supplement not supplant requirement in the ESEA while ensuring that Federal education funds provided through the title I, part A program meet their statutory purpose of providing students in high-poverty schools the extra resources they need to meet challenging State academic standards.

Clarity of the Regulations

Executive Order 12866 and the Presidential memorandum "Plain Language in Government Writing" require each agency to write regulations that are easy to understand.

The Secretary invites comments on how to make these proposed regulations easier to understand, including answers to questions such as the following:

- Are the requirements in the proposed regulations clearly stated?
- Do the proposed regulations contain technical terms or other wording that interferes with their clarity?
- Does the format of the proposed regulations (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity?
- Would the proposed regulations be easier to understand if we divided them into more (but shorter) sections? (A "section" is preceded by the symbol "§" and a numbered heading; for example, § 200.72 Supplement Not Supplant.)
- Could the description of the proposed regulations in the **SUPPLEMENTARY INFORMATION** section of this preamble be more helpful in making the proposed regulations easier to understand? If so, how?
- What else could we do to make the proposed regulations easier to understand?

To send any comments that concern how the Department could make these proposed regulations easier to understand, see the instructions in the **ADDRESSES** section.

Regulatory Flexibility Act Certification

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities. Under the U.S. Small Business Administration's Size Standards, small entities include small governmental jurisdictions such as cities, towns, or school districts (LEAs) with a population of less than 50,000. Although the majority of LEAs that receive ESEA funds qualify as small entities under this definition, the proposed regulations would not have a significant economic impact on these small LEAs because they would not require the expenditure of additional State and local education funds, only that existing State and local funding be allocated fairly to all schools, including both title I and non-title I schools. The Department believes the benefits of this proposed regulatory action would outweigh the burdens on these small LEAs of complying with the proposed regulations. In particular, the proposed regulations would clarify the supplement not supplant requirements in the ESEA while ensuring that Federal education funds meet their statutory purpose. The proposed regulations recognize the circumstances that small LEAs might face with respect to supplement not supplant requirements, allowing an LEA that uses the "special rule" option to exclude from the calculation of its average per-pupil spending funds spent in a school that enrolls fewer than 100 students. The Secretary invites comments from small LEAs as to whether they believe the proposed regulations would have a significant economic impact on them and, if so, requests evidence to support that belief.

Paperwork Reduction Act of 1995

As part of its continuing effort to reduce paperwork and respondent burden, the Department provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps ensure that: the public understands the Department's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

Proposed § 200.72(b)(1)(i)(A) and § 200.72(b)(1)(ii)(C) contains an information collection requirements. Under the PRA, the Department has submitted a copy of these sections to OMB for its review.

A Federal agency may not conduct or sponsor a collection of information unless OMB approves the collection under the PRA and the corresponding information collection instrument displays a currently valid OMB control number. Notwithstanding any other provision of law, no person is required to comply with, or is subject to penalty for failure to comply with, a collection of information if the collection instrument does not display a currently valid OMB control number.

In the final regulations, we will display the control number assigned by OMB to any information collection requirements proposed in this NPRM and adopted in the final regulations.

Proposed § 200.72(b)(1)(i)(A) would require each LEA to annually publish its methodology for allocating State and local funds in a manner easily accessible to the public. We estimate that during the three year period for which we seek information collection approval, 14,000 LEAs would devote five hours to publishing a methodology for allocating State and local funds. Therefore, we estimate for this section a total burden over three years for all respondents would be 70,000 hours, resulting in an average annual burden of 23,333 hours.

Proposed § 200.72(b)(1)(ii)(C) would allow States to—at their discretion—submit an alternate funds-based compliance test for Federal peer review that then could be used by LEAs to demonstrate compliance with the proposed supplement not supplant requirements. We estimate over the three year period for which we seek information collection approval, 15 States would choose to submit an alternate funds-based compliance test for Federal peer review, and that each State would devote 48 hours to preparing and submitting the alternate funds-based compliance test. Therefore, we anticipate the total burden over three years for all respondents would be 720 hours, resulting in an average annual burden of 240 hours for this section. In total, we estimate a burden of 23,573 hours for this proposed regulation.

COLLECTION OF INFORMATION

Regulatory section	Information collection	OMB Control No. and estimated burden
§ 200.72(b)(1)(i)(A)	This proposed regulatory provision would require each LEA to annually publish its methodology for allocating State and local funds.	OMB 1810–NEW. We estimate this would require 23,333 burden hours.
§ 200.72(b)(1)(ii)(C)	This proposed regulatory provision would allow States to submit an alternate funds-based compliance test for Federal peer review.	OMB 1810–NEW. We estimate this would require 240 burden hours.

If you want to comment on the proposed information collection requirements, please send your comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for U.S. Department of Education. Send these comments by email to *OIRA_DOCKET@omb.eop.gov* or by fax to (202) 395–6974. You may also send a copy of these comments to the Department contact named in the **ADDRESSES** section of this preamble.

We have prepared an Information Collection Request (ICR) for this collection. In preparing your comments you may want to review the ICR, which is available at *www.reginfo.gov.* Click on Information Collection Review. This proposed collection is identified as proposed collection 1810–NEW.

We consider your comments on this proposed collection of information in—

- Deciding whether the proposed collection is necessary for the proper performance of our functions, including whether the information will have practical use;
- Evaluating the accuracy of our estimate of the burden of the proposed collection, including the validity of our methodology and assumptions;
- Enhancing the quality, usefulness, and clarity of the information we collect; and
- Minimizing the burden on those who must respond. This includes exploring the use of appropriate automated, electronic, mechanical, or other technological collection techniques.

OMB is required to make a decision concerning the collection of information contained in these proposed regulations between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, to ensure that OMB gives your comments full consideration, it is important that OMB receives your comments by October 6, 2016. This does not affect the deadline for your comments to us on the proposed regulations.

Intergovernmental Review

This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Federalism

Executive Order 13132 requires us to ensure meaningful and timely input by State and local elected officials in the development of regulatory policies that have federalism implications. "Federalism implications" means substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Although we do not believe the proposed regulations would have federalism implications, we encourage State and local elected officials to review and provide comments on these proposed regulations.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* Braille, large print, audiotape, or compact disc) on request to the person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

List of Subjects in 34 CFR Part 200

Education of disadvantaged, Elementary and secondary education, Grant programs—education, Indians—education, Infants and children, Juvenile delinquency, Migrant labor, Private schools, Reporting and recordkeeping requirements.

Dated: August 26, 2016.

John B. King, Jr.,

Secretary of Education.

For the reasons discussed in the preamble, the Secretary proposes to amend part 200 of title 34 of the Code of Federal Regulations as follows:

PART 200—TITLE I—IMPROVING THE ACADEMIC ACHIEVEMENT OF THE DISADVANTAGED

■ 1. The authority citation for part 200 continues to read as follows:

Authority: 20 U.S.C. 6301–6576 (unless otherwise noted).

■ 2. Section 200.72 is revised to read as follows:

§ 200.72 Supplement not supplant.

(a) *In general.* (1) An SEA or LEA—

(i) Must use title I, part A funds only to supplement the funds that would, in the absence of the title I, part A funds, be made available from State and local sources for the education of students participating in title I programs; and

(ii) May not use title I, part A funds to supplant the funds from State and local sources.

(2) An LEA is not required under this section to—

(i) Identify that an individual cost or service supported with title I, part A funds is supplemental; or

(ii) Provide services with title I, part A funds through a particular instructional method or in a particular instructional setting.

(b) *Compliance*—(1) *Annual demonstration*—(i) *In general.* To comply with paragraph (a) of this section, an LEA must annually—

(A) Publish its methodology for allocating State and local funds in a format and language, to the extent practicable, that parents and the public can understand; and

(B) Demonstrate, at such time and in such form as the SEA may reasonably require, that the methodology it uses to allocate State and local funds to each title I school ensures that the school receives all of the State and local funds it would otherwise receive if it were not a title I school.

(ii) *LEA options.* In order to demonstrate that an LEA meets this requirement, the LEA must distribute almost all State and local funds available to the LEA in a way that meets one of the following tests:

(A) *Distribution of State and local funds based on characteristics of students.* An LEA distributes State and local funds to its schools according to a consistent districtwide per-pupil formula based on the characteristics of students in each school, such that—

(*1*) Students with characteristics associated with educational disadvantage, including students living in poverty, English learners, students with disabilities, and other such groups of students the LEA determines are associated with educational disadvantage, generate additional funding for their school; and

(*2*) Each title I school receives for its use all of the funds to which it is entitled under the formula.

(B) *Distribution of State and local funds based on personnel and non-personnel resources.* An LEA distributes State and local funds to its schools based on a consistent districtwide personnel and non-personnel resource formula such that each Title I school receives for its use an amount of actual State and local funds at least equivalent to the sum of—

(*1*) The average districtwide salary for each category of school personnel (*e.g.,* teachers, principals, librarians, school counselors), multiplied by the number of school personnel in each category assigned by the districtwide formula to the school; and

(*2*) The average districtwide per-pupil expenditure for non-personnel resources, multiplied by the number of students in the school.

(C) *Distribution of State and local funds based on an SEA-established compliance test.* (*1*) An LEA distributes State and local funds in a manner chosen by the LEA that—

(*i*) Is applied consistently districtwide; and

(*ii*) Meets a funds-based compliance test established by the SEA that is as rigorous as the approaches described in paragraph (b)(1)(ii)(A) or (B) of this section and has been approved through a Federal peer review process that relies upon peers such as professionals with expertise in school finance, State education officials, local education officials, and individuals who represent the interests of special populations of students. An SEA is not required to establish such a test; nor is an LEA required to use such a test if the LEA complies with paragraphs (b)(1)(ii)(A) or (B) or (b)(1)(iii) of this section.

(*2*) A funds-based compliance test that is "as rigorous as the approaches described in paragraph (b)(1)(ii)(A) or (B)" is one that results in substantially similar amounts of State and local funding for title I schools in the district as would the use of approaches described in paragraph (b)(1)(ii)(A) or (B), as determined by a Federal peer review process.

(iii) *Special Rule.* Notwithstanding paragraph (b)(1)(ii) of this section, an LEA may distribute State and local funds using any methodology that results in the LEA spending an amount of State and local funds per pupil in each title I school that is equal to or greater than the average amount of State and local funds spent per pupil in non-title I schools, as reported under section 1111(h)(1)(C)(x) of the ESEA.

(A) *De minimis annual variation.* An LEA may be considered in compliance with the special rule in paragraph (b)(1)(iii) of this section in a specific year if the amount of State and local funds each title I school receives is no more than 5 percent less than the average amount received by non-title I schools in that year.

(B) *Schools with fewer than 100 students.* In demonstrating compliance with the special rule in paragraph (b)(1)(iii) of this section, an LEA may exclude from its calculations any school that enrolls fewer than 100 students.

(C) *Demonstrating compliance.* An LEA may demonstrate compliance with the special rule in paragraph (b)(1)(iii) of this section if it demonstrates to the SEA that—

(*1*) One or more non-title I schools in the LEA receive additional funding to serve a high proportion of students with disabilities, English learners, or students from low-income families and these additional expenditures disproportionately affect the amount of State and local funds allocated, on average, to non-title I schools in the LEA or in a particular grade span within the LEA; and

(*2*) Absent such school or schools, the LEA would be in compliance.

(2) *Flexibilities.* (i) An LEA may demonstrate compliance with paragraph (b)(1) of this section on a districtwide or a grade-span basis.

(ii) An LEA is not required to meet the requirements in paragraph (b)(1) of this section—

(A) If it has a single school; or

(B) In any grade span in which it has a single school.

(iii) For purposes of demonstrating compliance under paragraph (b)(1) of this section, an LEA may exclude supplemental State or local funds expended for programs that meet the intent and purposes of title I, part A.

(iv)(A) To the extent that an LEA spends State or local funds for districtwide activities, the LEA may exclude those funds from its demonstration of compliance with paragraph (b)(1) of this section, provided that each title I school receives a share of those activities equal to or greater than the share it would otherwise receive if it were not a title I school, and the LEA distributes to schools under paragraph (b)(1) of this section almost all of the State and local funds available to it for current expenditures as defined in section 8101(12) of the ESEA.

(B) Districtwide activities—

(*1*) May include, for example, districtwide administrative costs, districtwide programs such as summer school or preschool, and personnel providing districtwide services such as curriculum development or data analyses; but

(*2*) May not include personnel or non-personnel resources associated with an individual school.

(3) *Transition timeline.* (i) No later than December 10, 2017, an LEA must—

(A) Demonstrate to the SEA that it has a methodology for allocating State and local funds to schools that meets the requirements in paragraph (b) of this section that the LEA will use no later than the 2018–2019 school year; or

(B) Submit a plan to the SEA for how it will fully implement a methodology that meets the requirements in paragraph (b) of this section beginning no later than the 2019–2020 school year.

(ii) Prior to either the 2018 – 2019 or 2019 – 2020 school year, as applicable under paragraph (b)(3)(i) of this section, an LEA may use either—

(A) The method of compliance it will use to comply with paragraph (b) of this section; or

(B) The method of compliance it used for complying with the applicable title I supplement not supplant requirement in effect on December 9, 2015.

(4) *Rules of construction.* (i) Nothing in this section shall be construed to require the forced or involuntary transfer of any school personnel.

(ii)(A) Nothing in this section shall be construed to require equalized spending per pupil for a State, LEA, or school.

(B) Equalized spending per pupil means equal expenditures per pupil as reported under section 1111(h)(1)(C)(x) of the ESEA.

(iii) Nothing in this section requires an LEA to adopt a specific methodology to allocate State and local funds to comply with the supplement not supplant requirement.

(iv) Nothing in this section shall be construed to alter or otherwise affect the rights, remedies, and procedures afforded to school or LEA employees under Federal, State, or local laws (including applicable regulations or court orders) or under the terms of collective bargaining agreements, memoranda of understanding, or other agreements between such employers and their employees.

(Authority: 20 U.S.C. 6321(b) and (d))

[FR Doc. 2016–20989 Filed 9–2–16; 8:45 am]

BILLING CODE 4000–01–P

POSTAL SERVICE

39 CFR Part 501

Revisions to the Requirements for Authority To Manufacture and Distribute Postage Evidencing Systems

AGENCY: Postal Service™.

ACTION: Proposed rule.

SUMMARY: The Postal Service proposes a further revision to the rules concerning PC postage payment methodology. This change would add supplementary information to clarify the revenue assurance guidelines.

DATES: Submit comments on or before October 6, 2016.

ADDRESSES: Mail or deliver written comments to the Manager, Payment Technology, U.S. Postal Service®, 475 L'Enfant Plaza SW., Room 3500, Washington DC 20260. You may inspect and photocopy all written comments at the Payment Technology office by appointment only between the hours of 9 a.m. and 4 p.m., Monday through Friday by calling 1–202–268–7613 in advance. Email and faxed comments are not accepted.

FOR FURTHER INFORMATION CONTACT: Marlo Kay Ivey, Business Systems Analyst, Payment Technology, U.S. Postal Service, (202) 268–7613.

SUPPLEMENTARY INFORMATION: On July 17, 2015, the United States Postal Service published a final rule to revise the rules concerning authorization to manufacture and distribute postage evidencing systems and to reflect new revenue assurance practices (80 FR 42392). Postage collection under the new rules will start on March 20, 2017. This document proposes additional changes with regard to revenue assurance which would support our efforts to collect the appropriate revenue on mail pieces in a more automated fashion. If adopted, the proposed clarifying changes would also be implemented on March 20, 2017. The revenue assurance guidelines can be found in 39 CFR 501.16, and on *https://ribbs.usps.gov* in the site index of Automated Package Verification (APV) documents, named *APV Standard Operating Procedure (SOP).*

List of Subjects in 39 CFR Part 501

Administrative practice and procedure.

Accordingly, for the reasons stated, the Postal Service proposes to amend 39 CFR part 501 as follows:

PART 501—AUTHORIZATION TO MANUFACTURE AND DISTRIBUTE POSTAGE EVIDENCING SYSTEMS

■ 1. The authority citation for 39 CFR part 501 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 410, 2601, 2605, Inspector General Act of 1978, as amended (Pub. L. 95–452, as amended); 5 U.S.C. App. 3.

■ 2. In § 501.16, revise paragraph (i) to read as follows:

§ 501.16 PC postage payment methodology.

* * * * *

(i) *Revenue assurance.* (1) The PC Postage provider must support business practices to assure Postal Service revenue and accurate payment from customers. For purposes of this paragraph and the Automated Package Verification (APV) Standard Operating Procedure (SOP) document available at *https://ribbs.usps.gov/index.cfm?page=apvs, PC Postage provider* and *PC Postage vendor* shall mean *providers* who offer *PC Postage products* (as such terms are defined in § 501.1) and shall also include Click-N-Ship and postage resellers when such resellers transmit postage revenue to the Postal Service in any manner other than through a PC Postage provider. With respect to such transactions, the resellers, and not the PC Postage providers who provide the labels, are responsible for complying with this paragraph. For the purpose of this paragraph, a *reseller* is an entity that obtains postage through a PC Postage provider and is authorized to resell such postage to its customers pursuant to an agreement with the Postal Service. For example, an entity that sells postage to its customers, but uses a PC Postage provider to enable its customers to print postage labels, is a "reseller" hereunder. If that entity collects postage revenue from its customers and transmits it to the Postal Service directly (instead of through the PC Postage provider) that entity shall be deemed a "PC Postage provider" hereunder.

(2)(i) For the purposes of this paragraph, a *postage adjustment* is defined as the difference between the postage or fee paid for a service offered by the Postal Service and the published or negotiated rate for that service indicating the postage due to the Postal

Service, at the time the mail piece is entered into the mailstream.

(ii) When the collection of a postage adjustment or the provision of a refund is appropriate because a customer has underpaid or overpaid the amount of postage that should have been paid, and such postage adjustment exceeds a threshold amount to be set by the Postal Service from time to time in its sole discretion, the PC Postage provider shall, upon the Postal Service's request, take steps to pay, collect, or refund, as applicable, the postage adjustment. The Postal Service will supply the PC Postage provider with the details necessary to explain the correction and the amount of the postage adjustment to be used in the adjustment process. As part of this process, the PC Postage provider shall enable customers to submit electronic disputes of postage collections to the Postal Service.

(iii)(A) In the case of an underpayment that exceeds the threshold amount, the PC Postage provider is required to pay the postage adjustment directly to the Postal Service; notify the customer and take steps to collect the postage adjustment, including but not limited to adjusting the funds available to the customer in the Postage Evidencing System; or (if directed by the Postal Service) facilitate customer payment by invoicing the customer or using other methods available to access funds of the customer.

(B) In the case of an overpayment that exceeds the threshold amount, the PC Postage provider is required to notify the customer and take steps to refund the postage adjustment or provide a credit to the customer.

(C) In either case, the PC Postage provider is required to address any postage discrepancies within a time period to be set by the Postal Service not to exceed 60 calendar days after initial notification by the Postal Service, subject to any applicable notification periods and dispute mechanisms that may be available to customers for these corrections.

(iv)(A) When an underpayment has occurred, the PC Postage provider shall prohibit the customer from printing additional postage labels until the postage adjustment is satisfied. The Postal Service may, in its sole discretion, waive or delay this prohibition in specific instances.

(B) Separately, in certain cases, such as where a customer is suspected of having intentionally or repeatedly underpaid postage, the Postal Service may, in its sole discretion, instruct the PC Postage provider to temporarily suspend or permanently shut down a customer's ability to print PC Postage, and the PC Postage provider shall promptly comply with such instruction.

(v) The Postal Service, in its sole discretion, may adopt and modify from time to time, and the PC Postage providers shall comply with, business rules, developed in conjunction with the PC Postage providers setting forth processes (including time constraints) for payments, refunds, collections, notifications, dispute resolutions and other activities to be performed hereunder.

(3)(i) Without regard to any threshold, if the PC Postage provider incorrectly programmed postage rates, delayed programming postage rate changes, or otherwise provided systems or software which caused customers to pay incorrect postage amounts, then within two calendar weeks of the PC Postage provider being made aware of such error, the PC Postage provider shall:

(A) Correct the programming error; and

(B) Provide the Postal Service with a detailed breakdown of how the error affected the PC Postage provider's collection of revenue.

(ii) Without regard to any threshold, in the event of an underpayment, the PC Postage provider shall pay the Postal Service for the postage deficiency, except in instances where the error was caused by the Postal Service.

(4) The PC Postage provider is responsible for ensuring that:

(i) All customers pay (and the Postal Service receives) the current published prices or their negotiated contracted prices that are available to mailers who purchase postage through an approved PC Postage provider, in accordance with this paragraph; and

(ii) All payments to the Postal Service (or the log files necessary for the Postal Service to collect payments directly from customers) are complete and accurate and are initiated or transmitted, as applicable, to the Postal Service each day.

(5) Each PC Postage provider:

(i) Is responsible for informing customers and obtaining electronic acceptance from customers to ensure that customers are informed, understand and agree to these payment terms, including that customers may be charged for deficient payments before their initial software installation is completed;

(ii) Shall comply with applicable laws, rules and regulations and ensure that its Postage Evidencing System, software, interfaces, communications and other properties that are used to sell or market postal products accurately describe such products;

(iii) Shall cover any costs that the Postal Service may incur as a result of such PC Postage provider or its employees, contractors, or representatives failing to comply with the terms of this section; or any applicable law, regulation, rule, or government policy; and

(iv) In performing its obligations hereunder, shall comply with the APV SOP and all agreed-to interface documentation (as updated from time to time).

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–21258 Filed 9–2–16; 8:45 am]

BILLING CODE 7710–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 217

[Docket No. 160405311–6664–01]

RIN 0648–BF95

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Rehabilitation of the Jetty System at the Mouth of the Columbia River: Jetty A, North Jetty, and South Jetty, in Washington and Oregon; Correction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; correction; extension of public comment period.

SUMMARY: This document corrects a typographical error in the **ADDRESSES** section to a proposed rule published on August 25, 2016.

DATES: Comments on the proposed rule must be submitted no later than October 6, 2016.

ADDRESSES: You may submit comments on this document identified by NOAA–NMFS–2016–0108, by any of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov,* enter NOAA–NMFS–2016–0108 in the "Search" box, click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910.

Instructions: Comments must be submitted by one of the above methods to ensure that the comments are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Rob Pauline, NMFS, (301) 427–8408, *robert.pauline@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Need for Correction

In the **ADDRESSES** section of a proposed rule (81 FR 58443; August 25, 2016) on page 58443, in the first column, NMFS used an incorrect document identifier number "NOAA–NMFS–2014–0144" rather than the correct document identifier of "NOAA–NMFS–2016–0108" in the Federal e-Rulemaking Portal hyperlink. The **ADDRESSES** section has been corrected in this document.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 30, 2016.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2016–21275 Filed 9–2–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 151116999–6759–01]

RIN 0648–BF52

Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; Electronic Monitoring Program

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes approval of, and regulations to implement, measures in a regulatory amendment to the Pacific Coast Groundfish Fishery Management Plan (FMP). The regulatory amendment was developed by the Pacific Fishery Management Council (Council) to implement an electronic monitoring (EM) program for two sectors of the limited entry trawl fishery. The regulatory amendment proposes to allow catcher vessels in the Pacific whiting fishery and fixed gear vessels in the shorebased Individual Fishing Quota (IFQ) fishery to use EM in place of observers to meet the requirements of the Trawl Rationalization Program for 100-percent at-sea observer coverage. This action is intended to increase operational flexibility and reduce monitoring costs for vessels in the trawl fishery by providing an alternative to observers. Data from the EM program would be used to debit discards of IFQ species from IFQs and mothership cooperative allocations. The regulatory amendment would establish an application process for interested vessel owners, performance standards for EM systems, requirements for vessel operators, and a permitting process and standards for EM service providers. The regulatory amendment would also establish requirements for processors (first receivers) for receiving and disposing of prohibited and protected species from EM trips.

DATES: Comments must be received by October 6, 2016.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2016–0115, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2016-0115,* click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Barry Thom, Acting Regional Administrator, West Coast Region, NMFS, 7600 Sandpoint Way NE., Seattle, WA 98115–0070; Attn: Melissa Hooper.
- *Fax:* 206–526–4461; Attn: Melissa Hooper.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

Copies of the regulatory amendment and draft analysis prepared by the Council are available from Chuck Tracy, Executive Director, Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384. The Regulatory Impact Review (RIR), draft environmental assessment (EA), and Initial Regulatory Flexibility Analysis (IRFA) prepared for this action are accessible via the Internet at *http://www.westcoast.fisheries.noaa.gov/fisheries/groundfish_catch_shares/electronic_monitoring.html.* The IRFA assessing the impacts of the proposed measures on small entities and describing steps taken to minimize any significant economic impact on such entities is summarized in the Classification section of this proposed rule. Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule should be submitted to the Acting Regional Administrator at the address above and to the Office of Management and Budget (OMB) by email to *OIRA_Submission@omb.eop.gov,* or fax to (202) 395–7285.

FOR FURTHER INFORMATION CONTACT: Melissa Hooper, Fishery Policy Analyst, phone: 206–526–4357, fax: 206–526–4461.

SUPPLEMENTARY INFORMATION:

Background

The Pacific Coast Groundfish FMP specifies management measures for over 90 different species of rockfish, flatfish, roundfish, sharks, skates, and other species, in Federal waters off the West Coast states. Target species in the commercial fishery include Pacific hake (whiting), sablefish, dover sole, and rockfish, which are harvested by vessels using primarily midwater and bottom trawl gear, but also fish pots and hook and line. The trawl fishery is managed under a catch share program called the Trawl Rationalization Program, which was implemented through Amendment 20 to the FMP in January 2011. The Program consists of an IFQ program for the shorebased trawl fleet (including whiting and non-whiting sectors), and cooperatives for the at-sea mothership and catcher/processor trawl fleets (whiting only). Concurrently, Amendment 21 established long-term allocations of certain groundfish species for the limited entry trawl sectors, which are used to determine what proportion of each species individual cooperatives and vessels can harvest. Annual catch limits are set on a two-year cycle through the biennial harvest specifications process. The 2017–2019 harvest specifications are under development by the Council and NMFS and intended to take effect January 1, 2017.

As part of the catch share program, Amendment 20 implemented requirements for 100 percent monitoring at-sea and dockside in order to ensure accountability for all landings and discards of allocated species. Catcher processors and motherships are required to carry two observers at all times, depending on the length of the vessel, and catcher vessels are required to carry one observer, including while in port until all fish are offloaded. In addition, first receivers, which are processors that are licensed to receive IFQ landings, are required to have catch monitors to monitor 100-percent of IFQ offloads. Vessel owners and first receivers are responsible for obtaining and funding catch share observers and catch monitors as a necessary condition of their participation in the program. However, NMFS subsidized the cost of observers for the first 5 years of the program to assist the industry in transitioning to the catch share program. The amount of the subsidy declined each year and ended in September 2015.

Faced with the costs of 100-percent monitoring, the industry raised concerns about their ability to support these costs and the need for an alternative to meet the monitoring requirements of the program. EM uses cameras and associated sensors to passively record and monitor fishing activities. The video can be reviewed by an analyst onshore at a later time to collect catch and effort information. EM has the potential to reduce monitoring costs because it does not require deploying a person on the vessel and the logistical and travel expenses that generates. EM was tested by the whiting fishery through Exempted Fishing Permits (EFPs) from 2004 to 2011 and by the Pacific States Marine Fisheries Commission (PSMFC) in the whiting fishery and with other gear types in 2012–2014. EM has been successfully deployed in British Columbia, Canada, to monitor fishing operations, and more recently in the U.S. Atlantic highly migratory species (HMS) fishery.

In response to industry's concerns, the Council initiated development of a regulatory amendment in November 2012 to implement an EM program for the shorebased and mothership sectors that would allow catcher vessels to use EM in place of observers to meet the at-sea monitoring requirements of the catch share program. Prior to Amendment 20, the Council had been developing an EM program for the Pacific whiting fishery in Amendment 10, but had set the action aside to prioritize work on the catch share program. The Council incorporated the Amendment 10 program in Amendment 20, making the whiting fishery a maximized retention fishery (all catch, with few exceptions, must be landed), and allowing for EM to be used in place of observers. However, the requirements of the EM program were not sufficiently developed to be implemented with the rest of the catch share program at that time. This regulatory amendment would specify the detailed requirements necessary to implement this provision of Amendment 20 for two components of the trawl fishery—catcher vessels using midwater trawl gear to target whiting in the mothership and shorebased sectors and trawl-permitted vessels using fixed gear to target other species in the shorebased sector. The regulatory amendment originally contemplated measures for all gear types, but the Council chose to postpone measures for bottom trawl and non-whiting midwater trawl vessels to a subsequent action to allow more time for development and analysis.

The Council had completed development of these measures in 2014, but postponed final action and instead approved four EFPs to test the proposed measures in the fishery. These EFPs would be used to provide data to analyze the effectiveness of the measures and to develop detailed requirements and procedures that would be necessary to implement the program. NMFS approved and issued the EFPs in May, 2015. A total of 34 vessels using a range of gear types participated in 2015, and 47 signed up in 2016. The Council reviewed the results of the 2015 EFPs at their meetings during the fall 2015-spring 2016 and took final action on the measures for whiting and fixed gear vessels at their April, 2016 meeting. Implementation of this action is targeted for November, 2016, with the intent for vessels to begin fishing with EM under the regulations in January, 2017.

Proposed Measures

The measures proposed by the regulatory amendment are described below. To implement these measures NMFS is proposing to revise the trawl fishery regulations in §§ 660.13, 660.19, 660.130, 660.140, and 660.150, to allow for vessel owners to use EM in place of an observer and establishes new regulations in §§ 660.600–660.604 governing its use. The proposed regulations were deemed by the Council to be consistent with the regulatory amendment and necessary to implement such provisions pursuant to section 303(c) of the Magnuson-Stevens Act through an August 16, 2016, letter from the Council Chairman to the NMFS Regional Administrator.

1. Overview of the EM Program

The regulatory amendment proposes to implement an EM program for Pacific whiting catcher vessels in the shorebased and mothership sectors and fixed gear vessels in the shorebased sector of the groundfish fishery. Vessel owners would be able to apply to NMFS to receive an exemption from the 100-percent observer coverage requirement, provided that they use an EM system and follow the catch handling, reporting, and other requirements of the EM program. Vessel owners authorized to use EM would be required to obtain an EM system from a NMFS-permitted service provider, as well as services to install and maintain the EM system, and to process, store, and report EM data to NMFS. Vessel operators would be required to submit a logbook reporting their discards of IFQ species. NMFS would use the logbook data to debit discards of IFQ species from IFQs and cooperative allocations, and use the EM data to audit the logbook data. EM data would also be used to monitor compliance with the requirements of the catch share program. NMFS's incremental costs to administer the EM program would be recoverable through Trawl Program cost recovery fees. The requirements of the program for vessel owners, operators, first receivers, and service providers, are described in more detail in the following sections.

As proposed in the Council's regulatory amendment, vessel owners would be responsible for the costs of procuring EM equipment and services from NMFS-permitted EM service providers. However, NMFS is still developing the standards and protocols that it would use to oversee service providers processing the EM data to ensure adequate data quality. Therefore, NMFS intends to conduct the data processing itself during 2017–2019 through PSMFC, contingent on available appropriations. Provided NMFS has sufficient funding, during 2017–2019 vessel operators would be responsible for procuring EM equipment and maintenance services from EM service providers. The requirement for vessel owners to obtain and fund data processing, storage, and reporting services would take effect January 1, 2020. This phased approach is reflected in the proposed regulations. In addition, because NMFS's ability to fund the video review is contingent upon appropriations which are not guaranteed, NMFS retains the ability in the regulations to implement the requirement for vessel owners to obtain data services earlier. In such a case, NMFS would provide at least six months prior notice to service providers and vessel owners before implementing the requirements.

In the proposed EM program, vessel operators would submit logbook reports which would be used initially to debit discards from IFQ vessel accounts and cooperative allocations. The video would later be reviewed by an analyst to determine an estimate of discards to use to audit the logbook reports. The Council also considered using EM discard estimates as the primary source for debiting discards in the whiting fishery, because it was thought that logbooks would be an unnecessary burden to vessels operators in the whiting fishery where estimating discards from the video is relatively quick. In addition, whiting industry representatives supported reviewing 100-percent of the video, and logbooks are primarily employed to allow a subsample of video to be reviewed in an audit model. However, through the 2015 EFPs, the Council and NMFS realized the value of the logbooks for communication between the vessel operator and the video reviewer about system malfunctions, for data quality assurance, and for aligning discard estimates. Therefore, the Council proposed a logbook audit model for both fixed gear and whiting vessels.

The Council proposes that initially 100 percent of the video be reviewed to audit the logbooks, but that NMFS may modify this percentage over time based on performance and in consultation with the Council. The Council also considered requiring 100 percent of the video to always be reviewed, because it would provide more certainty for discard estimates than extrapolating total discards from a subsample. However, reviewing 100 percent of the video is generally more costly than reviewing a subsample and erodes the potential savings that EM can provide relative to observers. For this reason, other EM programs implemented to date, such as the U.S. Atlantic HMS, British Columbia groundfish, and Australian programs, review a percentage of the video to audit vessel reports. Because an objective of the regulatory amendment was to reduce monitoring costs for the fleet, the Council also selected an audit approach for the west coast EM program. However, the Council also tied the level of review to program performance to ensure that data quality for catch accounting is maintained.

Discards estimated by the EM program, from logbook or EM data, would be debited from IFQs and cooperative allocations. The Council considered other alternatives for whiting trips that would have deducted small amounts of discards from ACLs, sector-wide, or cooperative allocations, preseason using estimates developed from historical observer data. It was believed that allowing video reviewers to ignore many small events during the video review might expedite the video review and reduce data processing costs. However, through the 2015 EFPs, the Council and NMFS learned that whiting hauls can be reviewed very quickly and that eliminating these discard events from review would not result in much cost savings. Therefore, the Council proposed debiting all discards from IFQs and cooperative allocations to provide the strongest incentive to minimize bycatch and discards.

Under the proposed EM program, Pacific halibut discards would be debited using discard mortality rates rather than viability assessments. Currently, observers on IFQ trips conduct viability assessments of all or a subsample of discarded halibut, which are a bycatch species in the groundfish fishery. Observers assign a score to the discarded halibut based on the results of the viability assessment which are used as an indication of whether the halibut is likely to survive after release. Based on the score given, a portion of the halibut's weight, rather than the total weight, may be deducted from a vessel's halibut Individual Bycatch Quota (IBQ). Observers will no longer be present to conduct viability assessments on EM trips, so NMFS would instead use discard mortality rates developed by the International Pacific Halibut Commission (IPHC) to deduct halibut IBQ from vessel accounts (18 percent for pots, 16 percent for longline, and 100 percent for midwater trawl). The West Coast Groundfish Observer Program (WCGOP) currently uses these rates to estimate mortality of halibut caught as bycatch in other west coast fisheries that have less than 100-percent observer coverage. PSMFC is currently conducting a study on bottom trawl trips to determine if viability can be estimated from information that can be collected from EM and logbooks. NMFS may revise the discard mortality rates at a future time to incorporate the results of this project or other new information, in consultation with the IPHC, to continue to use the best scientific information available to estimate halibut mortality.

Although vessel owners would be exempt from the requirement to obtain a catch share observer while using EM, vessel owners would still be required to carry an observer if requested by NMFS. Prior to the catch share program, NMFS deployed WCGOP observers on a percentage of trips in the trawl fishery to collect information for estimating mortality and bycatch, and to collect biological samples and other information. When the catch share program was implemented with a requirement for 100-percent industry-funded observer coverage, NMFS suspended its WCGOP coverage and reallocated these resources to monitor other fisheries; the catch share observers were able to serve dual purposes, collecting the information necessary to monitor compliance with the catch share program as well as other information such as biological samples and bycatch data. With the implementation of EM, NMFS is reinstituting the WCGOP coverage in the trawl fishery for EM trips. The EM program is intended to monitor discards of IFQ species for catch accounting, as well as compliance with the regulations. The EM program is not intended to collect all the other information that an observer collects, such as biological samples and bycatch information. Therefore, NMFS would use WCGOP coverage to continue to collect such information from the trawl fishery for use in groundfish mortality and bycatch estimates, stock assessments, and the standardized bycatch reporting methodology (SBRM). At this time, NMFS intends to deploy WCGOP observers on fixed gear trips, but not whiting trips because bycatch rates in the whiting fishery are low and nearly all catch is delivered and sampled by port samplers and mothership observers. However, NMFS would retain the authority in the regulations to deploy observers on whiting trips in a future fishing year with prior notice, if it was determined to be necessary.

2. Measures for Which NMFS Is Specifically Requesting Comments

Catch Retention Requirements

Under the proposed EM program, whiting vessels would continue to fish under the maximized retention requirements implemented in Amendment 20. However, NMFS is proposing to clarify the existing definition of "maximized retention" for the purposes of the EM program to make clear what types of discards are allowed (see proposed 50 CFR 660.604(p)(1)). The following discards would be permitted on whiting trips as "minor operational discards": Mutilated fish, large animals (longer than 6 feet (1.8 meters) in length), fish spilled from the codend during transfer to the mothership, fish picked from the gear or washed from the deck during cleaning, and fish vented from an overfull codend. Discards of invertebrates, trash, and debris, and discard events outside the control of the vessel operator would also be allowed. Minor operational discards would not include discards as a result from taking more catch than is necessary to fill the hold (a.k.a. "topping off"), which would continue to be prohibited. Minor operational discards would also not include discards of fish from a tow that was not delivered. This occurs when there is not enough catch worth delivering to a mothership, or not of the desired species composition, sometimes called "test tows" or "water tows." These discards are currently allowed if first sampled by an observer, but in an EM program, an observer would no longer be onboard to sample the catch before discarding. In addition, as no catch from the haul would be delivered to either a mothership or a plant, there would be no species composition to extrapolate to the discarded weight. Because these tows can sometimes include overfished or endangered species, these discards will be prohibited under the EM program. All discards, regardless of the source, would be required to be reported in a discard logbook and included in mortality estimates or debited from allocations (for IFQ species).

This revised definition was not included in the version of the regulations that the Council deemed, because the need for clarification was not clear to NMFS until after the April Council meeting. Therefore, NMFS is proposing to revise the definitions here using its authority under section 305(d) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), which allows the Secretary of Commerce to implement regulations necessary to ensure that fishery management plans or amendments are carried out consistent with the Magnuson-Stevens Act. NMFS is specifically requesting comment on this proposed definition.

NMFS is also requesting comment on catch retention rules for fixed gear vessels. The Council's regulatory amendment proposed "optimized retention" for fixed gear vessels, in which vessels would be able to discard any species that could be differentiated on camera. The measure provided for the list of allowable discard species to be revised as technology and methods improve through the "routine process" under the FMP (see § 660.60(c)). At the time of the Council's final action, NMFS only had data from the 2015 EFPs in which fixed gear vessels tested maximized retention, retaining all catch until landing. NMFS was proposing to allow fixed gear vessels to test optimized retention in 2016, but the results were not yet available. As a result, the proposed regulations reflect the more conservative, and restrictive, maximized retention rules that were based on 2015 EFP results and that were deemed by the Council (see proposed § 660.604(p)(2)). Under the maximized retention option, fixed gear vessels would be required to retain IFQ species salmon, and non-IFQ rockfish, flatfish, and roundfish.

However, NMFS is also considering the optimized retention option and seeks public comment on both options. Under the optimized retention option, fixed gear vessels may discard all fish, except salmon. NMFS will select a final option, based on public comment and the results of the 2016 EFPs, in the final rule, if the proposed measures are approved. Under either option, fixed gear vessels would be required to retain salmon in order to ensure complete accounting for the incidental take statement (ITS), although fixed gear vessels rarely catch salmon.

Switching Between Observers and EM

The Council proposed a limit on the number of times a vessel may switch between using observers and using EM in the same year. Observer providers and the WCGOP expressed concerns during the development of the regulatory amendment that some vessels may try to maximize their flexibility by using an observer on some trips and EM on others. It may be advantageous for a captain to use an observer where they have higher bycatch of a species they would like to discard, and EM on other trips with lower bycatch. Observer providers and WCGOP try to match the number of trained observers and their distribution across ports to the needs of the fleet. Frequent switching would disrupt deployment planning for observers and potentially result in observers not being available when needed in a particular port. Although it is in a vessel owner's interest to plan ahead with their provider in order to ensure an observer is available to meet their needs, this does not always occur. The Council considered alternatives for limiting switching in order to minimize disruption.

During the Council's consideration of final action for fixed gear, NMFS proposed that vessel owners submit a tentative fishing plan each year that would describe their intentions to use EM or observers for the upcoming fishing year. The WCGOP and observer providers could then use this information for planning purposes. The fishing plan would not be binding on vessel owners, maintaining their operational flexibility, but would provide the information needed for planning observer demand. The Council supported this idea and, therefore, recommended no limit on switching for fixed gear vessels. However, the Council did not make this change to the whiting alternatives and, as a result, the proposed regulations include a limit on switching for whiting vessels (see proposed § 660.604(m). Whiting industry members did not anticipate switching between observers and EM and so did not oppose this measure at the April meeting.

NMFS believes the proposed limit on switching for whiting may be ineffective at preventing disruptions to observer planning, because it would still allow for last-minute switching. NMFS believes requiring whiting vessel owners to submit a tentative fishing plan as for fixed gear vessels would provide the information NMFS needs and with more notice. NMFS believes not revising this alternative for whiting was an oversight by the Council and is concerned there is a not a clear rationale for why this limit should be implemented for whiting, but not fixed gear vessels. Therefore, NMFS is specifically requesting comments on having a limit on switching for the whiting fishery and, if there is a limit, whether twice a year is an appropriate limit (with additional exceptions for EM system malfunctions).

Video Data Retention

As part of the data services provided to vessel owners by EM service providers beginning in 2020, EM service providers would be required to maintain records and EM data for a minimum of three years (see proposed § 660.603(m)(6)). Vessel owners would be responsible for the costs of this data storage, along with the other services rendered by the EM provider, as a condition of their participation in the program. This measure was discussed at the November 2015 and April 2016 Council meetings. NMFS initially recommended a five year retention period, based on the five year statute of limitations for violations of the Magnuson-Stevens Act, to provide NMFS and law enforcement personnel sufficient time to review discard data reported by vessels and service providers, detect compliance issues, and to determine if any of the video should be retained for additional time and uses. Some industry members are concerned about the costs of storing such a large amount of video data, as well as the potential for enforcement personnel or other entities to access it for other purposes. They would prefer the video data be destroyed after one year, and only the reports resulting from the video review be retained. As a compromise, NMFS proposed and the Council supported a three year retention period in the draft regulations. However, the Council also recommended that NMFS review this requirement before 2020 to determine if it can be reduced. NMFS is specifically requesting comment on whether a one, three, or five year, retention period is appropriate for video data.

3. Vessel Owner Responsibilities

Vessel owners interested in using EM would be required to obtain authorization from NMFS. There would be a two-step application process, starting with an initial application that NMFS would use to assess a vessel owner's eligibility (see proposed § 660.604(e)). After reviewing the application, NMFS would notify the vessel owner of their eligibility to use EM and to submit a final application. The final application would include a form signed by a representative of the EM service provider certifying that the EM system was installed according to the performance standards in the regulations (see proposed §§ 660.604(e)(3)(i) and 660.604(j)). The final application would also include a tentative fishing plan (see proposed § 660.604(e)(3)(ii)), which would be used by NMFS to plan WCGOP sampling and observer deployments, and a vessel monitoring plan (VMP), which would document the configuration of equipment and catch handling protocols on that particular vessel (see proposed § 660.604(e)(3)(iii)). NMFS would notify the vessel owner of its final decision after reviewing the final application and, if approved, issue the vessel an EM authorization. If an initial or final application is denied, a vessel owner would be able to appeal NMFS's decision following the permits appeals process at § 660.25(g). The EM authorization would be effective until a change in vessel ownership, until NMFS notifies the owner that they are no longer eligible for it, or if the vessel owner fails to renew it. The EM authorization would be automatically renewed provided a vessel owner submits a renewal form verifying their vessel monitoring plan and providing an updated fishing plan. If a renewal form is not submitted, the authorization would expire on December 31 of that year.

NMFS is proposing that vessel owners that participated in the EM EFPs only be required to complete a renewal form, because NMFS already has vessel monitoring plans and a performance history for these vessels, making a complete application process unnecessary. If approved, NMFS would mail renewal forms to EFP vessel owners upon publication of the final rule. New vessel owners interested in using EM in 2017 would be required to submit an application after publication of the final rule. Draft application materials may be viewed on the West Coast Region's Web site: *http://www.westcoast.fisheries.noaa.gov/fisheries/groundfish_catch_shares/electronic_monitoring.html.*

NMFS would develop and maintain EM Program Guidelines, which would document best practices and other information that NMFS would use to evaluate vessel monitoring plans submitted by vessel owners (see proposed § 660.600(b)). New applicants for an EM authorization this fall may view draft EM Program Guidelines on the West Coast Region's Web site: *http://www.westcoast.fisheries.noaa.gov/fisheries/groundfish_catch_shares/electronic_monitoring.html.* The draft guidelines provide guidance and a template for developing individual vessel monitoring plans.

Vessel owners would be able to make changes to the vessel monitoring plan at any time by submitting an amendment to NMFS (see proposed § 660.604(f)). The vessel monitoring plan is intended to be a living document and would be modified over time to reflect changes to the vessel's equipment and operations, provided that NMFS has accepted the amendments in writing.

4. Vessel Operator Responsibilities

An operator of a vessel with EM would be required to attend a mandatory training on EM requirements prior to beginning fishing with EM (see proposed § 660.604(b)(5)). NMFS may waive this requirement on a case-by-case basis, such as for those captains that successfully participated in the EM EFP. Vessel operators would also be required to maintain the EM system in good working order, including ensuring the EM system is powered and functioning throughout the trip, keeping cameras clean and unobstructed, and ensuring the system is not tampered with (see proposed § 660.604(l)(1). The vessel operator would be required to declare their intent to use EM to the Office of Law Enforcement (OLE) via the existing declaration process at § 660.13(d)(5) (also see proposed § 660.604(m)). The vessel operator would also be required to notify WCGOP 48-hours before each EM trip for purposes of planning observer coverage (see proposed § 660.604(n)). If selected to carry an observer, the vessel operator would not be able to depart on the trip without the observer, and would be required to accommodate the observer on that trip. The vessel operator would also be required to conduct a system functionality test before each trip to ensure the EM system is working properly before departing (see proposed § 660.604(l)(2)). If the EM system malfunctions, a vessel operator may be prevented from fishing or required to return to port until the EM system is repaired, depending on the nature of the malfunction (see proposed § 660.604(l)(3)). An EM vessel would not be allowed to fish with an EM system that is not able to record fishing activity, unless an observer is onboard. A vessel operator would always be allowed to obtain an observer at their own expense to continue fishing while the EM system is repaired. The vessel operator would also be responsible for ensuring the crew follow the catch handling instructions in the VMP (see proposed § 660.604(r)), for completing a logbook for each trip and submitting logbooks and hard drives to PSMFC according to the deadlines in the regulations (see proposed § 660.604(s)), and maintaining records for a minimum of three years (see proposed § 660.604(t)).

5. First Receiver Responsibilities

First receivers would be required to sort and dispose of any prohibited or protected species retained by EM vessels (see proposed § 660.604(u)). First receivers already have such disposition requirements for landings from Pacific whiting maximized retention trips. This action would expand the existing whiting sorting and disposition requirements to landings from all EM trips, including fixed gear trips. The first receiver would be required to do the following:

- Record all prohibited species on the electronic fish ticket and provide them to the catch monitor for recording.

- Dispose of prohibited and protected species in a manner that ensures it will not enter a commercial market.
- Sort eulachon and green sturgeon to species and report them on the electronic fish ticket. Whole green sturgeon would be required to be transferred to the NMFS Southwest Fisheries Science Center within 72-hours.
- Report and surrender albatross to the U.S. Fish and Wildlife Service (FWS).
- Report and surrender marine mammals and sea turtles to NMFS.

Neither prohibited nor protected species would be allowed to be retained for personal use, including by a vessel owner or crew member, or first receiver or processing crew member. Prohibited species suitable for human consumption may be donated if appropriate to a surplus food collection and distribution system or nonprofit charitable organization for the purpose of reducing hunger and meeting nutritional needs.

6. EM Service Provider Responsibilities

EM service providers interested in supplying EM equipment and services to the fishery would be able to apply to receive a permit from NMFS. A service provider would be able to apply to NMFS by submitting an application package that contains, among other things, information about the company's organizational structure, prior experience, criminal convictions, conflicts of interest, and an EM service plan describing how the EM service provider proposes provide services to the fishery to meet the requirements of the program (see proposed § 660.603(b)). The EM service plan contains a number of components (see proposed § 660.603(b)(1)(vii)), including a description of the applicant's plan for provision of services, communications, procedures for hiring and training staff, and procedures for tracking hard drives, data processing, reporting, archiving EM data. The EM Service Plan would also include detailed descriptions of the EM system to be deployed and software to be used for analysis. An applicant may be required to provide NMFS with copies of the equipment and software for testing and evaluation (see proposed § 660.603(b)(1)(viii)). NMFS would evaluate the application against the regulations and, if approved, issue the provider a permit. If denied, the provider may appeal NMFS's decision using the provider permit appeal process described at § 660.19. The provider permit would be effective until the company changes ownership, NMFS notifies the provider that the permit is no longer valid, or if the provider fails to renew it. A provider's permit would be automatically renewed provided it submits a complete renewal form attesting to the accuracy of the current EM service plan and other information. The EM service provider would be able to modify its service plan by submitting an amendment to NMFS (see proposed § 660.603(c)). The EM service plan is intended to be a living document and would be updated over time to reflect changes to the provider's operations. NMFS would maintain EM Program Guidelines for the EM service plan on its Web site to assist providers in developing their plans (see proposed § 660.600(b)). NMFS has posted draft application materials and EM Program Guidelines on its Web site: *http://www.westcoast.fisheries.noaa.gov/fisheries/groundfish_catch_shares/electronic_monitoring.html.*

As with observer and catch monitor providers, an EM service provider would be required to be free of any conflicts of interest and to have insurance coverage for their employees that provide services on the vessels (see proposed § 660.603(h)).

EM service providers would be required to provide field and technical support services to vessels with which they have a contract, including installing equipment to meet NMFS's performance standards and providing technical assistance and repair services (see proposed § 660.603(k)). The EM service provider would also be required to provide support to NMFS, including assistance in diagnosing and resolving technical issues and litigation support, free of charge to NMFS (see proposed § 660.603(l)).

Beginning in 2020, or when NMFS transitions video review responsibilities to third party providers, the EM service provider would responsible for processing EM datasets; submitting reports to NMFS of catch data, compliance issues, and technical issues; communicating feedback to vessel operators to improve data quality; maintaining EM program records, including raw video and processed EM datasets; and maintaining the confidentiality and security of EM data (see proposed § 660.603(m)). EM data would be confidential, as are observer data, consistent with Magnuson-Stevens Act requirements. The service provider would be responsible for ensuring its staff are fully trained to successfully execute these duties.

Classification

Except for those measures identified above where NMFS is requesting specific comment, NMFS has made a preliminary determination that the measures this proposed rule would implement are consistent with the Pacific Coast Groundfish FMP, Magnuson-Stevens Act and other applicable laws. In making the final determination, NMFS will take into account the data, views, and comments received during the comment period.

This proposed rule has been determined to be not significant for the purposes of Executive Order (E.O.) 12866.

This proposed rule does not contain policies with Federalism or "takings" implications as those terms are defined in E.O. 13132 and E.O. 12630, respectively.

An IRFA was prepared, as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA, which includes this section of the preamble to this rule and analyses contained in its accompanying EA and RIR/IRFA, describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble.

Description and Estimate of Number of Small Entities to Which the Rule Will Apply

This regulatory amendment impacts mainly commercial harvesting entities engaged in the groundfish limited entry trawl fishery. Although this action proposes an EM program for only two components of the limited entry trawl fishery—the Pacific whiting fishery and the fixed gear shorebased IFQ fishery—any limited entry trawl vessel may participate in these components, provided they comply with its requirements, and therefore may be eligible to use EM. In addition, vessels deploying EM are likely to be a subset of the overall trawl fleet, as some vessels would likely choose to continue to use observers. However, as all trawl vessels could potentially use EM in the future, this IRFA analyzes impacts to the entire trawl fleet.

A general description of the limited entry trawl fishery and catch share program is contained in the preamble to this section. Most recent permit information indicates that there are approximately 175 limited entry trawl permits. According to information from the Northwest Fishery Science Center Economic Data Collection Program, in 2014, the fourth year of the catch share program, there were 102 catcher vessels that participated in the West Coast Groundfish Trawl Catch Share program. Catcher vessels generated $85 million in income and 954 jobs from deliveries of fish caught in the catch share program. Catcher vessels spent an average of 62 days fishing in the catch share program and spent an average of 80 additional days fishing in non-catch share fisheries. West Coast catcher vessels deliver to ports in Washington, Oregon, California, and at-sea; the two ports with the highest landings in 2014 were Astoria and Newport, both in Oregon. An average of 2.4 crew members worked aboard each West Coast catcher vessel, each earning an average compensation of $54,500. In 2014, 31 percent of vessels were owner-operated at least part of the year. The average ex-vessel revenue per vessel from participation in the catch share program was $646,000. Average variable cost net revenue (ex-vessel revenue minus variable costs) per vessel was $256,000 from participation in the catch share program, and the fleet-wide variable cost net revenue was $26.2 million. Average total cost net revenue (ex-vessel revenue minus variable costs and fixed costs) per vessel was $127,000 and the fleet-wide total cost net revenue was $12.9 million (NWFSC, 2014; *http://www.pcouncil.org/wp-content/uploads/2016/06/G5b_NMFS_Rpt4_MS_ElecVer_JUN2016BB.pdf*). These are preliminary results and it should be noted that some industry members have questioned the results of EDC data which is based on cost-earnings surveys where all participants are required to respond to. Via the Pacific Fishery Management Council's Five Year IFQ Trawl Program Review, the NWFSC economists will be meeting with the industry to further validate their results with the industry.

With respect to monitoring costs, the NWFSC 2014 EDC report states the following: "One other change resulting from the implementation of the catch share program was a shift to 100% observer coverage with partial industry funding. Prior to catch shares, there was approximately 20% observer coverage, paid for by NMFS. In order to lessen the cost of transitioning to the required 100 percent observer coverage, catcher vessels received a maximum subsidy of $328.50 per day in 2011 and 2012. This subsidy decreased in 2013 to $256 per day and in 2014 to $216 per day. Catcher vessels spent on average $14,400 on observer coverage (excluding the NMFS subsidy payments) while operating in the catch share program in 2014. In 2011, observer costs represented 0.6% of total costs, and increased to 2.8 percent in 2014. Note that as observer subsidies have decreased over time, the average expenses per vessel have increased. For this reason, the average 2014 costs reported will not reflect the costs currently incurred by the fleet." It should be noted that the 2015 observer subsidy was about $108 per day. The subsidy program ended in September 2015. Currently the industry is paying about $500 per day for observers.

This rule would apply to those entities that elect to use EM in lieu of observers. In 2015, a total of 36 vessels participated in the EM program. This total includes 20 vessels that participated in the Pacific whiting fishery (11 that participated in both the shorebased and mothership sectors, 9 that fished only in mothership) and 7 fixed gear vessels. This is likely an underestimate of the number of vessels that would use EM in the future. For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. For for-hire fishing and fish processing entities, the Small Business Administration (SBA) defines a small business as one that is: Independently owned and operated; not dominant in its field of operation; has annual receipts not in excess of $7.0 million in the case of for-hire fishing entities; or if it has fewer than 500 employees in the case of fish processors, or 100 employees in the case of fish dealers. When applying for their permits, entities were asked to classify themselves as a small business based on the finfish standard of $20.5 million. Only 5 indicated that they were "large" businesses and thus would continue to be large businesses under the $11.0 million standard. In 2015, ex-vessel revenues for all west coast fisheries for the remaining vessels ranged from $1,000 to $1.4 million. In 2014, "other fisheries revenue" collected on these vessels ranged from $0 to $5.0 million. Based on these ranges, NMFS concludes that the remaining vessels would be considered "small" even after factoring in the possibility of the vessels participating in Alaska fisheries.

Impacts of the Action on Small Entities

This action contains two major alternatives—the Council's preferred alternative and proposed action, to allow vessels in the groundfish fishery to use EM in place of observers, and the no action alternative, which would not create an EM option. The regulatory amendment also considered several sub-options for design elements within the preferred alternative, which are described in the accompanying EA and summarized in the preamble. This rule proposes to implement the Council's preferred alternative.

The proposed action is presenting a choice to fishermen—they can either continue to pay for 100-percent observer coverage or elect to pay for EM (*i.e.,* equipment, maintenance, and video review). Using 2015 EFP cost estimates developed jointly by PSMFC and NMFS, NMFS developed a model for assessing the vessel, fleet, and government costs from the preferred alternative. The results indicate economic impacts on small entities from the preferred alternative would be positive as these entities would have a choice of between hiring an observer and using EM. The current cost of an observer is approximately $500 per day. Presumably, vessel owners would choose between using an observer or EM based on relative costs and operational flexibility. NMFS estimates indicate fixed gear vessels will save approximately $98 per day, mothership catcher vessels $159 per day, and shoreside vessels $330, using EM. Vessels that participated in the EFPs already own EM systems (most whiting vessels and approximately half of the fixed gear vessels), so they may see a greater cost savings compared to new entrants, until such time that the cameras need to be replaced. Annual vessel estimates show fixed gear and mothership catcher vessels saving $3,000 to $4,000 and shoreside whiting vessels saving $24,000 per year, relative to the cost of observers. Annual fleet estimates show similar results.

In addition to the direct costs of the program, vessel owners would be responsible for reimbursing NMFS for its incremental costs for administering the EM program. NMFS collects cost recovery fees to cover the incremental costs of management, data collection, and enforcement of the trawl rationalization program. Fees are limited to a maximum of 3 percent of ex-vessel revenues. NMFS's incremental costs for administering the shorebased sector already exceed 3 percent, so the shorebased sector would not be likely to see an increase in fees from the preferred alternative in the short term. The mothership sector fees are currently 1.25 percent of ex-vessel revenue, so NMFS would be able to recover this sector's portion of EM program costs by increasing the fees.

As mentioned in the preamble to this proposed rule, NMFS intends to conduct the video review itself for 2017–2019, contingent on available funding, while the standards and protocols that would be used to certify and oversee third party service providers are developed. The requirement for industry to fund the video review would take effect in 2020, or earlier if NMFS does not have funding to process the data itself. When video review responsibilities shift to third party providers, NMFS's and PSMFC's responsibilities would be reduced to oversight and quality assurance, which may include auditing the service providers' video review results. To conservatively estimate government costs and corresponding fee increases, NMFS assumes that service providers would review 100 percent of the video and that NMFS would audit 50 percent of the video. Government costs include video review and storage costs, as well as program management costs, statistician costs, database management, and overhead. With the full transition in 2020, NMFS estimates the government costs would be approximately $286,000 per year. Under current fee rates, only the portion of the costs related to the mothership catcher vessel fleet would be recouped by the cost recovery fee, which would result in an increase of 0.02 percent. NMFS estimates that compared to the costs of observers, the preferred alternative would still present a lower cost option for whiting and fixed gear vessels.

Under Alternative 2, seven sub-options were developed to address various aspects of program design. These sub-options are summarized in the preamble to this proposed rule. Generally speaking, the Council's sub-options would either have no effect on the overall cost of the program (sub-options A2, D1, E1), reduce the cost of the program (sub-options E1, B1), or provide industry additional flexibility (sub-options C2, F1, G1-Fixed Gear, G2-Whiting).

Measures Proposed To Mitigate Adverse Economic Impacts of the Proposed Action

There are no significant alternatives to the proposed action that would accomplish the stated objectives and that minimize any significant economic impact of the proposed rule on small entities. Alternatives that were considered and rejected, and the reason the Council or NMFS rejected them, are summarized in Section 3.3 of the EA. The other sub-options considered, and the reasons the Council and NMFS did not propose them, are summarized in the preamble to this proposed rule. As fishermen would be given a choice between two alternative monitoring systems (observers versus EM), this rule is likely to have positive effects on small entities. NMFS believes that the preferred alternative for this rule would not have a significant impact when comparing small versus large businesses in terms of disproportionality and profitability given available information. These regulations are likely to reduce fishing costs for both small and large businesses. Nonetheless, NMFS has prepared this IRFA. Through this proposed rule, NMFS is requesting comments on this conclusion. The proposed action and alternatives are described in detail in the Council's regulatory amendment and the accompanying EA and RIR/IRFA (see **ADDRESSES**).

Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements

The proposed action contains a collection-of-information requirement subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement will be submitted to OMB for approval. The proposed action does not duplicate, overlap, or conflict with any other Federal rules.

This action proposes to adjust notification requirements for groundfish vessels using EM and first receivers receiving catch from EM trips. Vessels would now be required to declare the type of monitoring they will use on a given trip—observer or EM. This change is necessary to provide vessels the flexibility to switch between different types of monitoring, depending on what is most cost effective and efficient for their operation at that time, while allowing NMFS to track which fleets vessels are participating in. The proposed change would only add additional potential answers to an existing question and not affect the number of entities required to comply with the declaration requirement (OMB Control Number 0648–0573). Therefore, the proposed change would not be expected to increase the time or cost burden associated with this requirement. Similarly, the requirement for EM vessels to notify the observer program before each trip would be in place of the existing notification to an individual vessel's observer provider when using a catch share observer, and would not be expected to increase the time or cost burden associated with the existing notification requirements approved under OMB Control Number 0648–0593. The requirement for first receivers to report protected and prohibited species landings was previously approved under OMB Control Number 0648–0619 and this action would not be expected to change the time or cost burden or number of entities associated with this requirement.

This action proposes to require vessel owners to submit an application to NMFS to be approved to use EM in place of an observer. This application would include an application form, the purchase or lease and installation of an EM system, a VMP, and attendance of a mandatory training session. The time burden associated with these requirements is estimated to be approximately 10 hours per vessel owner to prepare and submit the application package, install the EM system, and attend training. The training would be given via webinar to maximize convenience and minimize travel costs for vessel captains. Based on comments from industry participants during the development of the regulations, NMFS is proposing that vessel owners and captains that participated in the EFPs complete an abbreviated application process for 2017 to reduce the time burden to them. The cost of an EM system and installation is estimated at $12,000 per vessel. Approximately half the active vessels in the fleet have already received EM units through their participation in the EFPs and would not need to purchase a new unit to participate in the program. Vessel owners would likely have to purchase new EM units every 5–10 years, depending on the life of the equipment. Vessel owners would also be responsible for maintaining the EM units in good working order, likely through a service contract with a NMFS-permitted EM service provider. NMFS estimates the annual average cost burden per vessel from this requirement to be approximately $5,600.

If denied an EM Authorization, vessel owners would be able to appeal NMFS's decision through the existing appeal process at § 660.25(g). NMFS estimates the time burden associated with preparing and submitting an appeal to be approximately 4 hours per entity, with a cost of $3.00 for copies and postage. Vessel owners would be able to make modifications to their VMPs during the year by submitting a request and amended VMP to NMFS. These requests would be made electronically via email and, therefore, would not be expected to have a cost burden associated with them. NMFS estimates the time burden associated with this requirement from preparing and submitting the request to be 0.5 hours per request per entity.

Vessel owners would be required to renew their EM authorization annually. This is necessary to ensure that the vessel owners' contact information, VMPs, and fishing plans remain up to date. Industry participants raised concerns with the time burden associated with having to complete the application process each year, as was proposed in an earlier draft of the regulations. To address these concerns, NMFS is proposing to instead provide vessel owners with pre-filled renewal forms and their current VMPs to review and certify as correct in a simplified renewal process. NMFS estimates a time burden of approximately 0.5 hours per entity to review and return the pre-filled package.

Vessel operators would be required to complete and submit a logbook for each trip, with an estimated time burden of 10 minutes per submission. The logbooks are provided by NMFS and state agencies, so the cost of requirement mainly derives from postage at $0.46 per submission. To eliminate duplication, NMFS would allow vessel operators to submit a state logbook that contains all the required information. Vessel operators would also be required to submit the hard drive containing video data to NMFS (in 2017–2019) or the EM service provider (2020–beyond) using a method that provides a return receipt. This is necessary for NMFS and vessel operators to be able to track submissions. This requirement has an average cost of $15.00 per submission and a time burden of 10 min to retrieve and package the hard drive for mailing.

EM service providers would be required to apply to receive a permit from NMFS to provide EM services in the fishery. EM service providers would be required to submit an application to NMFS that includes an application form, an EM Service Plan that describes how they plan to provide services to the fishery, and statements of prior experience and qualifications. If requested, the EM service provider may also be required to provide NMFS copies of contracts with vessel owners and standard operating procedures and manuals describing their operations in more detail. In an earlier draft of the regulations, NMFS proposed requirements very similar to those for observer service providers, with minimal requirements for the provider and NMFS training and certifying individual observers. However, at the November 2015 Council meeting EM service providers commented that different service providers may have different models and that this model is not appropriate for EM services providers. Some EM service providers may employ less highly trained analysts to initially review video and a biologist to verify species identification. Whereas another service provider may employ highly trained biologists to do it all. They recommended that the regulations provide more flexibility for different business models. This proposed rule contains an expanded application process, incorporating an EM Service Plan, to provide the flexibility that service providers seek. The addition of an EM Service Plan allows NMFS to consider different business models proposed by different providers as meeting the EM program requirements. However, this requires EM service providers prepare and submit a detailed service plan and other documents, in order to provide NMFS with sufficient information to evaluate them. NMFS estimates the time and cost burden associated with preparing and submitting the permit application to be 47 hours and $30 (for copies and postage). Most likely much of this information would be submitted electronically. If requested by NMFS, EM service providers would be required to provide NMFS two EM units and two copies of any software for EM data analysis for a minimum of 90 days for evaluation. Due to their use by NMFS, the value of the EM units may depreciate and the EM service providers may not be able to resell the EM units for their full value. NMFS estimates the EM providers would be able to recoup 50 percent of the EM unit value at approximately $5,000 per unit. This results in a total cost associated with this requirement at $10,215 per provider (including $215 in materials and postage to send the equipment to NMFS).

An EM service provider would be able to appeal a permit decision to NMFS following the procedures at § 660.19. NMFS estimates the time and cost burden of preparing and submitting an appeal to be 4 hours and $5 per entity. EM service providers would be able to make modifications to their EM Service Plans during the year by submitting a request and amended EM Service Plan to NMFS via email (2 hours per submission). EM service providers would be required to renew their permits annually. At the April 2016 Council meeting, EM service providers requested a longer effective period to provide more stability for planning for future fishing years. Therefore, in this proposed rule NMFS is proposing an abbreviated renewal process in which NMFS would provide pre-filled renewal forms and the current EM Service Plan for the EM service provider to review and certify. This would reduce the time burden for EM service providers, while ensuring NMFS has up-to-date information. NMFS estimates the annual time and cost burden of the renewal to be 1 hour and $5 per entity.

In 2017–2019, EM service providers would be responsible for providing technical assistance and maintenance services to EM vessels. EM service providers would be required to provide technical support to vessels at sea, with an annual time burden of approximately 7 hours per entity. EM service providers and their employees would also be required to report instances of non-compliance by vessel owners and intimidation or harassment of EM technicians to NMFS. The estimated burden for reporting these events is 30 minutes per report (18 hours per entity per year). Employees of EM service providers may be debriefed by NMFS or OLE on technical or compliance issues with an estimated burden of 1 hour per trip (350 hours per entity per year).

Beginning in 2020, EM service providers would also be responsible for reviewing video from trips, preparing and submitting catch data and compliance reports to NMFS, and providing feedback to vessel operators on their catch handling, camera views, etc. NMFS would prepare burden estimates for these requirements for OMB approval and public comment through a **Federal Register** notice in 2019 or earlier.

Public reporting burden for these requirements includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, and Indian fisheries.

Dated: August 26, 2016.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons stated in the preamble, NMFS proposes to amend 50 CFR part 660 as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*, 16 U.S.C. 773 *et seq.*, and 16 U.S.C. 7001 *et seq.*

■ 2. In § 660.13, revise paragraphs (d)(5)(ii) through (iv) to read as follows:

§ 660.13 Recordkeeping and reporting.

* * * * *

(d) * * *

(5) * * *

(ii) The vessel operator must send a new declaration report, consistent with paragraph (d)(5)(iv) before leaving port on a trip in which a gear type and monitoring type, if applicable, that is different from the gear type and monitoring type most recently declared for the vessel will be used. A declaration report will be valid until another declaration report revising the existing gear and monitoring declaration is received by NMFS OLE.

(iii) During the period of time that a vessel has a valid declaration report on file with NMFS OLE, it cannot fish with a gear and monitoring type other than a gear type and monitoring type declared by the vessel.

(iv) Declaration reports will include: The vessel name and/or identification number, gear type, and monitoring type where applicable, (as defined in paragraph (d)(5)(iv)(A) of this section). Upon receipt of a declaration report, NMFS will provide a confirmation code or receipt to confirm that a valid declaration report was received for the vessel. Retention of the confirmation code or receipt to verify that a valid declaration report was filed and the declaration requirement was met is the responsibility of the vessel owner or operator. Vessels using nontrawl gear may declare more than one gear type with the exception of vessels participating in the Shorebased IFQ Program (*i.e.* gear switching), however, vessels using trawl gear may only declare one of the trawl gear types listed in paragraph (d)(5)(iv)(A) of this section on any trip and may not declare nontrawl gear on the same trip in which trawl gear is declared.

(A) One of the following gear types or sectors, and monitoring type where applicable, must be declared:

(*1*) Limited entry fixed gear, not including shorebased IFQ,

(*2*) Limited entry groundfish non-trawl, shorebased IFQ, observer,

(*3*) Limited entry groundfish non-trawl, shorebased IFQ, electronic monitoring,

(*4*) Limited entry midwater trawl, non-whiting shorebased IFQ,

(*5*) Limited entry midwater trawl, Pacific whiting shorebased IFQ, observer,

(*6*) Limited entry midwater trawl, Pacific whiting shorebased IFQ, electronic monitoring,

(*7*) Limited entry midwater trawl, Pacific whiting catcher/processor sector,

(*8*) Limited entry midwater trawl, Pacific whiting mothership sector (catcher vessel or mothership), observer,

(*9*) Limited entry midwater trawl, Pacific whiting mothership sector (catcher vessel), electronic monitoring,

(*10*) Limited entry bottom trawl, shorebased IFQ, not including demersal trawl,

(*11*) Limited entry demersal trawl, shorebased IFQ,

(*12*) Non-groundfish trawl gear for pink shrimp,

(*13*) Non-groundfish trawl gear for ridgeback prawn,

(*14*) Non-groundfish trawl gear for California halibut,

(*15*) Non-groundfish trawl gear for sea cucumber,

(*16*) Open access longline gear for groundfish,

(*17*) Open access Pacific halibut longline gear,

(*18*) Open access groundfish trap or pot gear,

(*19*) Open access Dungeness crab trap or pot gear,

(*20*) Open access prawn trap or pot gear,

(*21*) Open access sheephead trap or pot gear,

(*22*) Open access line gear for groundfish,

(*23*) Open access HMS line gear,

(*24*) Open access salmon troll gear,

(*25*) Open access California Halibut line gear,

(*26*) Open access Coastal Pelagic Species net gear,

(*27*) Other gear,

(*28*) Tribal trawl, or

(*29*) Open access California gillnet complex gear.

* * * * *

■ 3. In § 660.19, revise paragraph (a) introductory text to read as follows:

§ 660.19 Appeals process for catch monitors, observers, and provider permits.

(a) *Allowed appeals.* This section describes the procedure for appealing IADs described at §§ 660.17(g), 660.18(d) and (f), 660.140(h), 660.150(j), 660.160(g), 660.603(b)(3) for catch monitor decertification, observer decertification, provider permit expirations due to inactivity, and EM service provider permit denials. Any person whose interest is directly and adversely affected by an IAD may file a written appeal. For purposes of this section, such person will be referred to as the "applicant."

* * * * *

■ 4. In § 660.130, revise paragraphs (d)(2)(ii) and (d)(3)(ii) to read as follows:

§ 660.130 Trawl fishery—management measures.

* * * * *

(d) * * *

(2) * * *

(ii) *Catcher vessels.* All catch must be sorted to the species groups specified in paragraph (d)(1) of this section for vessels with limited entry permits, except those engaged in maximized retention while declared into a Pacific whiting IFQ trip. The catch must not be discarded from the vessel and the vessel must not mix catch from hauls until the observer has sampled the catch, unless otherwise allowed under the EM Program requirements at § 660.604 of subpart J. Prohibited species must be sorted according to the following species groups: Dungeness crab, Pacific halibut, Chinook salmon, other salmon. Non-groundfish species must be sorted as required by the state of landing.

(3) * * *

(ii) If sorting occurs on a catcher vessel in the MS Coop Program, the catch must not be discarded from the vessel and the vessel must not mix catch from hauls until the observer has sampled the catch, or unless otherwise allowed under the EM Program requirements at § 660.604 of subpart J.

* * * * *

■ 5. In § 660.140, revise paragraph (g)(1) introductory text and add paragraph (h)(1)(i)(A)(*4*) to read as follows:

§ 660.140 Shorebased IFQ Program.

* * * * *

(g) * * *

(1) *General.* Shorebased IFQ Program vessels may discard IFQ species/species groups, provided such discards are accounted for and deducted from QP in the vessel account. With the exception of vessels on a declared Pacific whiting IFQ trip and engaged in maximized retention, and vessels fishing under a valid EM Authorization in accordance with § 660.604 of subpart J, prohibited and protected species must be discarded at sea; Pacific halibut must be discarded as soon as practicable and the discard mortality must be accounted for and deducted from IBQ pounds in the vessel account. Non-IFQ species and non-groundfish species may be discarded at sea, unless otherwise required by EM Program requirements at § 660.604 of subpart J. The sorting of catch, the weighing and discarding of any IBQ and IFQ species, and the retention of IFQ species must be monitored by the observer.

* * * * *

(h) * * *

(1) * * *

(i) * * *

(A) * * *

(*4*) Is exempt from the requirement to carry an observer if the vessel has a valid EM Authorization and is fishing with EM under § 660.604 of subpart J.

* * * * *

■ 6. In § 660.150, revise paragraphs (i) and (j)(1)(i)(B) to read as follows:

§ 660.150 Mothership (MS) Coop Program.

* * * * *

(i) *Retention requirements.* Catcher vessels participating in the MS Coop Program may discard minor operational amounts of catch at sea if the observer or EMS has accounted for the discard (*i.e.,* a maximized retention fishery).

(j) * * *

(1) * * *

(i) * * *

(A) * * *

(B) *Catcher vessels.* Any vessel delivering catch to any MS vessel must carry one certified observer each day that the vessel is used to take groundfish, unless the catcher vessel has a valid EM Authorization and is fishing with EM under § 660.604 of subpart J.

* * * * *

■ 7. Add subpart J to read as follows:

Subpart J—West Coast Groundfish Electronic Monitoring Program.

Sec.
660.600 Applicability.
660.601 Definitions.
660.602 Prohibitions.
660.603 Electronic monitoring provider permits and responsibilities.
660.604 Vessel and first receiver responsibilities.
660.600 Applicability.

Subpart J—West Coast Groundfish Electronic Monitoring Program

(a) *General.* This subpart contains requirements for vessels using EM in lieu of observers, as authorized under § 660.140(h)(1)(i) (Shorebased IFQ Program) and § 660.150(j)(1)(i) (MS Coop Program), and requirements for EM service providers. Vessel owners, operators, and managers are jointly and severally liable for a vessel's compliance with EM requirements under this subpart. This subpart also contains requirements for a first receiver receiving catch from a trip monitored by EM (*see* § 660.604(u)). The table below provides references to the sections that contain vessel owner, operator, first receiver, and service provider responsibilities. Certain requirements for vessel owners and operators and EM service providers will be different in 2020 and beyond.

West Coast groundfish fishery	Section
(1) Limited entry trawl fishery.	
(i) Vessel owners	§ 660.604
(ii) Vessel operators	§ 660.604
(iii) First receivers	§ 660.604
(iv) Service providers	§ 660.603
(2) [Reserved].	

(b) *EM program guidelines.* NMFS will develop EM Program Guidelines, which will document best practices and other information that NMFS will use to evaluate proposed service and vessel monitoring plans submitted by EM service providers and vessel owners under this subpart. NMFS will develop the EM Program Guidelines in consultation with the Council and publish notice of their availability in the **Federal Register**. NMFS will maintain the EM Program Guidelines on its Web site and make them available to vessel owners and operators and EM service providers to assist in developing service plans and vessel monitoring plans that comply with the requirements of this subpart.

§ 660.601 Definitions.

These definitions are specific to this subpart. General groundfish definitions are found at § 660.11, subpart C, and trawl fishery definitions are found at § 660.111, subpart D.

Active sampling unit means the portion of the groundfish fleet in which an observer coverage plan is being applied.

Discard control point means the location on the vessel designated by a vessel operator where allowable discarding may occur.

Discard event means a single occurrence of discarding of fish or other species.

Electronic Monitoring or *EM* consists of the use of an electronic monitoring system (EMS) to passively monitor fishing operations through observing or tracking.

Electronic Monitoring Authorization means the official document provided by NMFS that allows a vessel with a limited entry trawl permit to use electronic monitoring under the provisions of this subpart.

Electronic Monitoring System Certification Form means the official document provided by NMFS, signed by a representative of a NMFS-permitted electronic monitoring service provider that attest that an EM system and associated equipment meets the performance standards defined at § 660.604(j) of this subpart, as required by § 660.604(e)(3)(i).

EM data processing means the review, interpretation, and analysis of EM data (*i.e.,* video and sensor data).

EM Program means the Electronic Monitoring Program of the West Coast Region, National Marine Fisheries Service.

EM Program Manager means the Chief of the Permits and Monitoring Branch of the West Coast Region, National Marine Fisheries Service, or his designee.

EM Service Plan means the document that describes in detail how the EM service provider will provide EM services to the fishery to successfully achieve the purpose of the EM Program.

EM service provider means any person, including their employees or agents, that is granted a permit by NMFS to provide EM services as required under § 660.603 and § 660.604.

Electronic Monitoring System or *EMS* means a data collection tool that uses a software operating system connected to an assortment of electronic components, including video recorders, to create a collection of data on vessel activities.

EM technician means an employee of the EM service provider that provides support for EM systems and technical assistance to vessels and NMFS.

EM trip means any fishing trip for which electronic monitoring is the declared monitoring type.

Initial Administrative Determination (IAD) means a formal, written determination made by NMFS on an application or permit request that is subject to an appeal within NMFS.

Non-trawl shorebased IFQ vessel means a vessel on a declared limited entry groundfish non-trawl, shorebased IFQ trip.

Pacific whiting fishery refers to the Pacific whiting primary season fisheries described at § 660.131. The Pacific whiting fishery is composed of vessels participating in the C/P Coop Program, the MS Coop Program, or the Pacific whiting IFQ fishery.

Pacific whiting IFQ fishery is composed of vessels on Pacific whiting IFQ trips.

Pacific whiting IFQ trip means a trip in which a vessel uses midwater groundfish trawl gear during the dates of the Pacific whiting primary season to target Pacific whiting, and Pacific whiting constitutes 50 percent or more of the catch by weight at landing as reported on the state landing receipt. Vessels on Pacific whiting IFQ trips must have a valid declaration for limited entry midwater trawl, Pacific whiting shorebased IFQ.

Shorebased IFQ Program or *Shorebased IFQ sector,* refers to the fishery described at § 660.140, subpart D, and includes all vessels on IFQ trips.

Vessel Monitoring Plan (*VMP*) means the document that describes how fishing operations on the vessel will be conducted and how the EM system and associated equipment will be configured to meet the performance standards and purpose of the EM Program.

§ 660.602 Prohibitions.

In addition to the general prohibitions specified in § 600.725 of this chapter, it is unlawful for any person to:

(a) *Electronic monitoring program.*—(1) Make a false statement on an application for issuance, renewal, or changes to an EM Authorization or NMFS-accepted VMP.

(2) Fish for or land fish from a trip without electronic monitoring or observer coverage when a vessel is required to carry electronic monitoring or an observer under §§ 660.140(h) or 660.150(j).

(3) Fish for or land fish from a trip taken under electronic monitoring without a valid EM Authorization and NMFS-accepted vessel monitoring plan onboard, and a valid gear and monitoring declaration with NMFS OLE as required by § 660.604(c)(1) and § 660.604(m).

(4) Fail to comply with a NMFS-accepted VMP.

(5) Fail to notify the West Coast Groundfish Observer Program at least 48-hours prior to departing port of the vessel operator's intent to take a trip under EM, as required by § 660.604(n).

(6) Fail to conduct a pre-departure test prior to departing port as required by § 660.604(l)(2).

(7) Fish on an EM trip without a fully functional EM system, unless authorized by a NMFS-accepted VMP as required by § 660.604(l)(3).

(8) Fail to make the EM system, associated equipment, logbooks and other records available for inspection immediately upon request by NMFS OLE personnel or other authorized officers, as required by §§ 660.604(o) and 660.604(t).

(9) Discard species other than those allowed to be discarded as specified at § 660.604(p).

(10) Fail to handle fish and other marine organisms in a manner that enables the EM system to record it as required by § 660.604(r).

(11) Fail to submit complete and accurate logbook(s) and hard drive(s) for each EM trip as specified at § 660.604(s),

(12) Tamper with, disconnect, damage, destroy, alter, or in any way distort, render useless, inoperative, ineffective, or inaccurate any component of the EM system or associated equipment.

(13) Assault, resist, oppose, impede, intimidate, harass, sexually harass, bribe, or interfere with an EM service provider, EM field services staff, or EM data processing staff.

(14) Interfere with or bias the sampling procedure employed by EM data processing staff including either mechanically or manually sorting or discarding catch outside of camera view or inconsistent with the NMFS-accepted VMP.

(15) Fail to meet the vessel owner or operator responsibilities specified in section 660.604.

(16) Fail to meet the first receiver responsibilities specified at § 660.604(u).

(17) Fail to meet the EM service provider responsibilities specified in section 660.603.

(18) Fish when a vessel is required to carry an observer under subpart J of this part if:

(i) The vessel is inadequate for observer deployment as specified at § 600.746 of this chapter;

(ii) The vessel does not maintain safe conditions for an observer as specified at § 660.604(n);

(iii) NMFS, the observer provider, or the observer determines the vessel is inadequate or unsafe pursuant to vessel responsibilities to maintain safe conditions as specified at § 660.604(n);

(19) Fail to meet the vessel responsibilities and observer coverage requirements specified at § 660.604(n).

(b) [Reserved]

§ 660.603 Electronic monitoring provider permits and responsibilities.

(a) *General.* This section contains requirements for EM service providers providing EM services to vessels operating in the Shorebased IFQ Program (§ 660.140) or the MS Coop Program (§ 660.150) and using EM under this subpart. A person must obtain a permit and endorsement as provided under § 660.603(b) in order to be an EM service provider. An EM service provider must:

(1) Operate under a NMFS-accepted EM Service Plan (*see* § 660.603(b)(3)(vii)).

(2) Provide and manage EM systems, field services, and technical assistance as required under § 660.603(k);

(3) Provide technical and litigation support to NMFS or its agent (*see* § 660.603(l)).

(4) Provide technical support to fishing vessels 24-hours per day, seven days per week, and year-round as provided under § 660.603(k)(4);

(5) Beginning on January 1, 2020, or earlier if notified by NMFS, provide EM data processing, reporting, and record retention services to vessels using EM (*see* § 660.603(m)).

(6) Comply with data integrity and security requirements, including requirements pertaining to hard drives containing EM data, (*see* § 660.603(n)).

(b) *Provider permits.* To be an EM service provider, a person must obtain an EM service provider permit and endorsement by submitting an application to the NMFS West Coast Region Fisheries Permit Office. A person may meet some requirements of this section through a partnership or subcontract with another entity, in which case the application for an EM service provider permit must include information about the partnership. An applicant may submit an application at any time. If a new EM service provider, or an existing EM service provider seeking to deploy a new EMS or software version, submits an application by June 1, NMFS will issue a new permit by January 1 of the following calendar year. Applications submitted after June 1 will be processed as soon as practicable. NMFS will only process complete applications. Additional endorsements to provide observer or catch monitor services may be obtained under § 660.18.

(1) *Contents of provider application.* To be considered for an EM service provider permit and endorsement, the service provider must submit a complete application that includes the following information. The same information must be included for any partners or subcontractors if the applicant intends to satisfy any of the EM service provider requirements through a partnership or contractual relationship with another entity.

(i) Certify that the applicant meets the following eligibility criteria:

(A) The EM service provider and its employees do not have a conflict of interest as defined at § 660.603(h), and,

(B) The EM service provider is willing and able to comply with all applicable requirements of this section and to operate under a NMFS-accepted EM Service Plan.

(ii) Applicant's contact information.

(iii) Legal name of applicant organization. If the applicant organization is United States business entity, include the state registration number.

(iv) Description of the management, organizational structure, and ownership structure of the applicant's business, including identification by name and general function of all controlling management interests in the company, including but not limited to owners, board members, officers, authorized agents, and employees. List all office locations and their business mailing address, business phone, fax number, and email addresses. If the applicant is a corporation, the articles of incorporation must be provided. If the applicant is a partnership, the partnership agreement must be provided.

(v) A narrative statement describing prior relevant experience in providing EM services, technical support, or fishery data analysis services, including recruiting, hiring, training, deploying, and managing of individuals in marine work environments and of individuals working with fishery data, in the groundfish fishery or other fisheries of similar scale.

(vi) A statement signed under penalty of perjury by an authorized agent of the applicant about each owner, or owners, board members, and officers if a corporation, authorized agents, and employees, regarding:

(A) Conflict of interest as described in § 660.603(h),

(B) Criminal convictions,

(C) Federal contracts they have had and the performance rating they received on each contract, and

(D) Any previous history of decertification or permit sanction action while working as an observer, catch monitor, observer provider, catch monitor provider, or electronic monitoring provider.

(vii) *EM Service Plan.* An EM Service Plan that describes in detail how the applicant will provide EM services to the fishery sufficient to provide NMFS with the best scientific information available to determine individual accountability for catch, including discards, of IFQ species and compliance with requirements of the Shorebased IFQ Program (§ 660.140) and MS Coop Program (§ 660.150). NMFS will develop EM Program Guidelines containing best practices and templates and make them available on NMFS's Web site to assist EM service providers in developing EM Service Plans (*see* § 660.600(b)). The EM Service Plan must include descriptions of the following (using pictures and diagrams where appropriate):

(A) Contact information for a primary point of contact for program operations inseason;

(B) A plan for provision of services including communications, service locations, response timelines, and procedures for services, repairs, technical support, and other program services;

(C) Procedures for hiring and training of competent program staff to carryout EM field services and data services, including procedures to maintain the skills of EM data processing staff in:

(*1*) Use of data processing software;

(*2*) Species identification;

(*3*) Fate determination and metadata reporting requirements;

(*4*) Data processing procedures;

(*5*) Data tracking; and,

(*6*) Reporting and data upload procedures.

(D) Procedures for tracking hard drives throughout their use cycle, including procedures to ensure the integrity and security of hard drives in transit, and for removing confidential data from hard drives before returning them to the field;

(E) Procedures for data processing, including tracking of EM datasets throughout their processing cycle and documenting any access and modifications;

(F) Procedures for correction and resubmission of EM datasets that NMFS has determined are not sufficient, as described at § 660.603(m)(5), and to ensure that future datasets are sufficient for use by NMFS.

(G) Policies on data access, handling, and release to maintain the confidentiality of the EM Program data;

(H) Procedures for archiving of EM datasets and raw video, sensor and GPS data, etc., after reports have been submitted to NMFS;

(I) Identifying characteristics of the EMS to be deployed and the video review software to be used in the fishery, including but not limited to: Manufacturer, brand name, model name, model number, software version and date, firmware version number and date, hardware version number and date, monitor/terminal number and date, pressure sensor model number and date, drum rotation sensor model number and date, and GPS model number and date.

(J) EM system and software specifications, including a narrative statement describing how the EM system and associated equipment meets the performance standards at § 660.604(j).

(K) EM video review software specifications, including a narrative statement describing how the software is sufficient to provide NMFS with the best available information to determine individual accountability for catch, including discards, of IFQ species and compliance with requirements of the Shorebased IFQ Program (§ 660.140) and MS Coop Program (§ 660.150).

(viii) Provide NMFS the following, if requested:

(A) Two EM system units loaded with software for a minimum of 90 calendar days for testing and evaluation.

(B) Thorough documentation for the EM system, including: User manuals, any necessary interfacing software, performance specifications, technical support information, and tamperproof or tamper evident features.

(C) The results of at-sea trials of the EM system.

(D) Two copies of video review and analysis software for a minimum of 90 calendar days for testing and evaluation.

(E) Thorough documentation for the video review and analysis software, including: User manuals, performance specifications, and technical support information.

(F) Descriptions of database models and analysis procedures for program and fishery data to produce required reports.

(2) *Application evaluation.* NMFS may request additional information or revisions from the applicant until NMFS is satisfied that the application is complete. Complete applications will be forwarded to the EM Program for review and evaluation by the EM provider permit review board. If the applicant is an entity, the review board also will evaluate the application criteria for each owner, board member, officer, authorized agent, and employee. NMFS will evaluate the application based on the EM Program Guidelines (*see* § 660.600(b)) and the following criteria:

(i) The applicant's relevant experience and qualifications;

(ii) Review of any conflict of interest as described in § 660.603(h);

(iii) Review of any criminal convictions;

(iv) Review of the proposed EM Service Plan, including evaluation of EM equipment and software;

(v) Satisfactory performance ratings on any federal contracts held by the applicant;

(vi) Review of any history of decertification or permit sanction as an observer, catch monitor, observer provider, catch monitor provider, or EM service provider; and,

(vii) Review of any performance history as an EM service provider.

(3) *Agency determination on an application.* Based on a complete application, if NMFS determines that the applicant has met the requirements of this section, NMFS will issue an initial administrative determination (IAD). If the application is approved, the IAD will serve as the EM service provider's permit and endorsement. If the application is denied, the IAD will provide an explanation of the denial in writing. The applicant may appeal NMFS's determination following the process at § 660.19.

(4) *Effective dates.* The provider permit is valid from the effective date until occurrence of any one or more of the following:

(i) The EM service provider changes ownership;

(ii) December 31 of that year if the EM service provider fails to submit a complete renewal form for the following year; or,

(iii) NMFS notifies the EM service provider that its permit is invalid. NMFS may invalidate an EM service provider permit if NMFS determines that the EM service provider no longer meets the eligibility criteria defined at paragraph (b)(1)(i). NMFS will first notify the EM service provider of the deficiencies in writing and the EM service provider must correct the deficiencies following the instructions provided. If the deficiencies are not resolved upon review of the first trip following the notification, NMFS will notify the EM service provider in writing that the provider permit is invalid and that the EM service provider is no longer eligible to provide EM services to the fishery for the remainder of that calendar year. The EM service provider may reapply for an EM service provider permit and endorsement for the following calendar year.

(c) *Changes to a NMFS-accepted EM Service Plan.* An EM service provider may make changes to a NMFS-accepted EM Service Plan by submitting a revised plan or plan addendum to NMFS in writing. NMFS will review and accept the change if it meets all the requirements of this section. A plan addendum must contain:

(1) The date and the name and signature of an authorized agent of the EM service provider;

(2) Address, telephone number, fax number and email address of the person submitting the addendum;

(3) A complete description of the proposed EM Service Plan change.

(d) *Change of provider permit ownership and transfer restrictions.* If an EM service provider changes ownership during the term of an EM service provider permit, the new owner must apply for a new provider permit.

(e) *Provider permit sanctions.* Procedures governing sanctions of permits are found at subpart D of 15 CFR part 904.

(f) *Renewing a provider permit.* NMFS will mail renewal forms to existing EM service providers each year on or about April 15. If an EM service provider submits the completed renewal form by June 1, the EM service provider's permit and endorsement will be automatically renewed for the following calendar year.

(g) *Fees.* NMFS may charge a fee to cover administrative expenses related to issuance of permits including initial issuance, renewal, replacement, and appeals.

(h) *Limitations on conflict of interest for providers and employees.*—(1) EM service providers and their employees must not have a direct financial interest, other than the provision of observer, catch monitor, EM, or other biological sampling services, in any federal or state managed fisheries, including but not limited to:

(i) Any ownership, mortgage holder, or other secured interest in a vessel, first receiver, shorebased or floating stationary processor facility involved in the catching, taking, harvesting or processing of fish;

(ii) Any business involved with selling supplies or services to any vessel, first receiver, shorebased or floating stationary processing facility; or

(iii) Any business involved with purchasing raw or processed products from any vessel, first receiver, shorebased or floating stationary processing facilities.

(2) EM service providers and their employees must not solicit or accept, directly or indirectly, any gratuity, gift, favor, entertainment, loan, employment, or anything of monetary value from any person who conducts fishing or fish processing activities that are regulated by NMFS, or who has interests that may be substantially affected by the performance or nonperformance of the official duties of the provider.

(3) The EM service provider may not employ any person to handle hard drives or EM data from a vessel by which the person was previously employed in the last two years.

(4) Provisions of contracts or agreements for remuneration of EM services under this section do not constitute a conflict of interest.

(i) *Insurance.* The EM service provider must maintain adequate insurance (copies of which shall be provided to the vessel owner, operator, or vessel manager, when requested) to cover injury, liability, and accidental death to cover vessel owner, and the EM service provider and its employees, including the following:

(1) Maritime Liability to cover "seamen's" claims under the Merchant Marine Act (Jones Act) and General Maritime Law ($1 million minimum).

(2) Coverage under the U.S. Longshore and Harbor Workers' Compensation Act ($1 million minimum).

(3) States Worker's Compensation as required.

(4) Commercial General Liability.

(j) *Warranties.* None of the provisions of this section are intended to preclude any state or federal statutes or regulations governing warranties.

(k) *Field and technical support services.* The EM service provider must provide and manage EM systems, installation, maintenance and technical support, as described below, according to a NMFS-accepted EM Service Plan and such that the EM Program is sufficient to provide NMFS with the best scientific information available to determine individual accountability for catch, including discards, of IFQ species and compliance with requirements of the Shorebased IFQ Program (§ 660.140) and MS Coop Program (§ 660.150).

(1) At the time of installation, the EM service provider must:

(i) Install an EM system that meets the performance standards under § 660.604(j);

(ii) Ensure that the EM system is set up, wires run, system powered, and tested with the vessel in operation;

(iii) Brief the vessel operator on system operation, maintenance, and procedures to follow for technical support or field service;

(iv) Provide necessary information for the vessel operator to complete the VMP, such as images and diagrams of camera views and vessel layout, specific information about system settings, and designated discard control points; and,

(v) Complete an EM System Certification Form for the vessel owner.

(2) The EM service provider must communicate with vessel operators and NMFS to coordinate service needs, resolve specific program issues, and provide feedback on program operations.

(3) The EM service provider must provide maintenance and support services, including maintaining an EM equipment inventory, such that all deployed EM systems perform according to the performance standards at § 660.604(j) and that field service events are scheduled and carried out with minimal delays or disruptions to fishing activities.

(4) The EM service provider must provide technical assistance to vessels, upon request, in EM system operation, the diagnosis of the cause of malfunctions, and assistance in resolving any malfunctions. Technical support must be available 24-hours per day, seven days per week, and year-round.

(5) The EM service provider must submit to NMFS reports of requests for technical assistance from vessels, including when the call or visit was made, the nature of the issue, and how it was resolved.

(l) *Program and technical support for NMFS.* The EM service provider must provide the following to NMFS or its agent, upon request, free of charge unless otherwise specified by contract.

(1) Assistance in EM system operation, diagnosing and resolving technical issues, and recovering corrupted or lost data.

(2) Support for inquiries related to data summaries, analyses, reports, and operational issues with vessel representatives

(3) Litigation support to NMFS if the EM system/data is being admitted as evidence in a court of law. All technical aspects of a NMFS-approved EM system are subject to being admitted as evidence in a court of law, if needed. The reliability of all technologies utilized in the EM system may be analyzed in court for, inter alia, testing procedures, error rates, peer review, technical processes and general industry acceptance. The EM service provider must, as a requirement of the provider's permit, provide technical and expert support for litigation to substantiate the EM system capabilities or other relevant information to investigate or establish potential violations of this chapter or other applicable law, as needed, including:

(i) If the technologies have previously been subject to such scrutiny in a court of law, the EM service provider must provide NMFS with a brief summary of the litigation and any court findings on the reliability of the technology.

(ii) Sign a non-disclosure agreement limiting the release of certain information that might compromise the effectiveness of the EM system operations.

(4) Supply all software necessary for accessing, viewing, and interpreting the data generated by the EM system, including maintenance releases to correct errors in the software or enhance the functionality of the software.

(5) Notify NMFS within 24 hours after the EM service provider becomes aware of the following:

(i) Any information regarding possible harassment of EM provider staff;

(ii) Any information regarding possible EM system tampering;

(iii) Any information regarding any action prohibited under §§ 660.12(f) or 660.602(a)(13); and,

(iv) Any information, allegations or reports regarding EM service provider staff conflicts of interest.

(6) Notify NMFS of any change of management or contact information or a change to insurance coverage.

(7) If requested, provide NMFS with the following:

(i) A copy of any contract between the service provider and entities requiring EM services;

(ii) Proof of adequate insurance as defined in paragraph (i);

(iii) Copies of any information developed and used by the EM service provider and distributed to vessels, including, but not limited to, informational pamphlets, payment notifications, and description of EM service provider duties; and,

(iv) Access to and submit to NMFS raw EM imagery, sensor, GPS, or other data, processed data, copies of EM data, meta data, and other associated records.

(m) *Data services.* Beginning on January 1, 2020, or earlier if notified by NMFS in the **Federal Register** with six months prior notice, the EM service provider must provide and manage data processing, reporting, and record retention services, as described below, according to a NMFS-approved EM Service Plan and such that the EM Program is sufficient to provide NMFS with the best scientific information available to determine individual accountability for catch, including discards, of IFQ species and compliance with requirements of the Shorebased IFQ Program (§ 660.140) and MS Coop Program (§ 660.150).

(1) The EM service provider must process sensor and image datasets, interpret, and analyze EM data sets from EM trips. The EM provider must review EM data according to a prescribed coverage level or sampling scheme, as specified by NMFS, and determine an estimate of discards for each trip using standardized estimation methods specified by NMFS. NMFS will maintain manuals for EM data processing protocols on its Web site.

(2) The EM service provider must ensure that data processing staff are fully trained in:

(i) Use of data processing software;

(ii) Species identification;

(iii) Fate determination and metadata reporting requirements;

(iv) Data processing procedures;

(v) Data tracking; and,

(vi) Reporting and data upload procedures.

(3) The EM service provider must track hard drives and EM datasets throughout their cycles, including documenting any access and modifications. EM hard drives must be erased to remove confidential data before returning them to the field.

(4) The EM service provider must communicate with vessel operators and NMFS to coordinate data service needs, resolve specific program issues, and provide feedback on program operations. The EM service provider must provide feedback to vessel representatives, field services staff, and NMFS regarding:

(i) Adjustments to system settings;

(ii) Changes to camera positions;

(iii) Advice to vessel personnel on duty of care responsibilities;

(iv) Advice to vessel personnel on catch handling practices; and,

(v) Any other information that would improve the quality and effectiveness of data collection on the vessel.

(5) The EM service provider must submit to NMFS processed EM datasets and summaries, including discard estimates, fishing activity information, and meta data (*e.g.*, image quality, reviewer name), and incident reports of compliance issues as instructed by NMFS. EM datasets and reports must be sufficient to provide NMFS with the best scientific information avaialble to determine individual accountability for catch, including discards, of IFQ species and compliance with requirements of the Shorebased IFQ Program (§ 660.140) and MS Coop Program (§ 660.150). If NMFS determines that the information is not sufficient, NMFS may require the EM service provider to correct and resubmit the reports.

(6) *Retention of records.* Following an EM trip, the EM service provider must maintain all EM data and other records specified in this section, or used in the preparation of records or reports specified in this section or corrections to these reports, for a period of not less than three years after the date of landing for that trip. EM records must be stored such that the integrity and security of the records is maintained for the duration of the retention period. The EM service provider must produce EM records immediately upon request by the EM Program Manager or an authorized officer.

(n) *Data integrity and security.* The EM service provider must ensure the integrity and security of EM data and other records specified in this section.

(1) The EM service provider must not handle or transport hard drives containing EM data except to carry out EM services required by this section in accordance with a NMFS-accepted EM Service Plan.

(2) The EM service provider must not write to or modify any EM hard drive that contains raw EM data before it has been copied and catalogued.

(3) Consistent with the Magnuson-Stevens Act, an EM service provider and its employees must not disclose data and observations made on board a vessel to any person except the owner or operator of the observed vessel, an authorized state or an OLE agent or officer, NMFS or its designated agent.

§ 660.604 Vessel and first receiver responsibilities.

(a) *General.* This section lays out the requirements for catcher vessels to obtain an exemption to use electronic monitoring (EM) in place of 100-percent observer coverage required by the Shorebased IFQ Program

(§ 660.140(h)(1)(i)) and MS Coop Program (§ 660.150(j)(1)(i)(B)). Requirements are also described for first receivers receiving landings from EM trips.

(b) *Vessel Owner Responsibilities.* To use EM under this section, vessel owners must:

(1) Obtain an EM Authorization from the NMFS West Coast Region Fisheries Permit Office (*see* § 660.604(e));

(2) Install an EM system using a NMFS-permitted EM service provider that meets performance standards under § 660.604(j);

(3) Have a signed EM system certification form (*see* § 660.604(e)(3)(i));

(4) Have a NMFS-accepted vessel monitoring plan (*see* § 660.604(e)(3)(iii));

(5) Ensure that the vessel operator attends a mandatory EM orientation session provided by the NMFS West Coast Region EM Program (NMFS may waive this requirement on a case-by-case basis, such as when the vessel operator has prior EM experience);

(6) Maintain logbooks and other records for three years and provide them to NMFS or authorized officers for inspection (*see* § 660.604(t)).

(7) Beginning January 1, 2020, or earlier if notified by NMFS, obtain EM data processing and recordkeeping services from a NMFS-permitted EM service provider (*see* § 660.604(k)).

(c) *Vessel Operator Responsibilities.* To use EM under this section, vessel operators must:

(1) Maintain a valid EM Authorization and NMFS-accepted vessel monitoring plan onboard the vessel at all times that the vessel is fishing on an EM trip or when fish harvested during an EM trip are onboard the vessel;

(2) Ensure that the EM system is installed, operated, and maintained consistent with performance standards (*see* § 660.604(l));

(3) Comply with a NMFS-accepted vessel monitoring plan (*see* § 660.604(e)(3)(iii));

(4) Make declaration reports to OLE prior to leaving port (*see* § 660.604(m));

(5) Provide advance notice to the Observer Program at least 48 hours prior to departing port (*see* § 660.604(n));

(6) Comply with observer requirements, if NMFS notifies the vessel owner, operator, or manager that the vessel is required to carry an observer (*see* § 660.604(n));

(7) Ensure retention and handling of all catch as provided under §§ 660.604(p) and 660.604(r);

(8) Comply with recordkeeping, reporting and inspection requirements (*see* §§ 660.604(o), (s) and (t)); and,

(d) *First receiver responsibilities.* First receivers receiving catch from trips taken under EM must follow special disposition and sorting requirements for prohibited and protected species (*see* § 660.604(u)).

(e) *Electronic Monitoring Authorization.* To obtain an EM Authorization, a vessel owner must submit an initial application to the NMFS West Coast Region Fisheries Permit Office, then a final application that includes an EM system certification and a vessel monitoring plan (VMP). NMFS will only review complete applications. A vessel owner may submit an application at any time. Vessel owners that want to have their Authorizations effective for January 1 of the following calendar year must submit their complete application to NMFS by October 1. Vessel owners that want to have their Authorizations effective for May 15 must submit their complete application to NMFS by February 15 of the same year. Vessel owners that participated in the 2015 or 2016 EM Exempted Fishing Permit project may submit a completed renewal form to receive an EM Authorization for 2017, following the process at § 660.604(i).

(1) *Initial application.* To be considered for an EM Authorization, the vessel owner must submit a completed application form provided by NMFS, signed and dated by an authorized representative of the vessel, and meet the following eligibility criteria:

(i) The applicant owns the vessel proposed to be used;

(ii) The vessel has a valid Pacific Coast Groundfish limited entry, trawl-endorsed permit registered to it;

(iii) If participating in the mothership sector, the vessel has a valid MS/CV endorsement;

(iv) The vessel is participating in the Pacific whiting IFQ fishery, mothership sector, or the Shorebased IFQ sector using groundfish non-trawl gear;

(v) The vessel is able to accommodate the EM system, including providing sufficient uninterrupted electrical power, suitable camera mounts, adequate lighting, and fittings for hydraulic lines to enable connection of a pressure transducer;

(vi) The vessel owner and operator are willing and able to comply with all applicable requirements of this section and to operate under a NMFS-accepted vessel monitoring plan.

(2) *Review of initial application.* Based on a complete initial application, if NMFS determines that the applicant meets the eligibility criteria in paragraph (e)(1) of this section, NMFS will notify the applicant in writing that the initial application has been accepted for further consideration. An applicant who receives such notice may install an EM system on his or her vessel and proceed with submission of a final application as provided under paragraph (e)(3). If an initial application has not been accepted, NMFS will provide the applicant an explanation of the denial in writing. The applicant may appeal NMFS's determination following the process at § 660.25(g).

(3) *Final application.* A final application must be complete and must include:

(i) *EM system certification.* A certification form, provided by NMFS, signed by a representative of a NMFS-permitted EM service provider that attests that an EM system and associated equipment that meets the performance standards at paragraph (k) was installed on the vessel, that the system was tested while the vessel was underway, and that the vessel operator was briefed on the EM system operation and maintenance. NMFS will maintain a list of permitted EM service providers on its Web site.

(ii) *Tentative fishing plan.* A description of the vessel owner's fishing plans for the year, including which fishery the vessel owner plans to participate in, from what ports, and when the vessel owner intends to use EM and observers. This information is for purposes of planning observer deployments and is not binding.

(iii) *Vessel monitoring plan.* A complete vessel monitoring plan for the vessel that accurately describes how fishing operations on the vessel will be conducted and how the EM system and associated equipment will be configured to meet the performance standards at paragraph (k). NMFS will develop EM Program Guidelines containing best practices and templates and make them available on NMFS's Web site to assist vessel owners in developing VMPs (*see* § 660.600(b)). An EM service provider may prepare and submit a VMP on behalf of the applicant. The VMP must include descriptions of the following (using pictures and diagrams where appropriate):

(A) General vessel information including the vessel name, hull number, gear type(s), home port, captain name, and target fishery or sector;

(B) The coordinates of the home port box, if a geo-referenced port box will be used to trigger data collection;

(C) A diagram of the vessel layout with measurements of the deck and denoting the location of any designated discard control points;

(D) The number and location of cameras and with images of corresponding views;

(E) The location of lighting, control center, GPS, sensors, monitor, and other EM equipment;

(F) Frame rates, image resolution, frequency of data logging, sensor trigger threshold values, and other EM system specifications;

(G) The location and procedures for any catch handling, including designated discard control points within camera view, procedures for sorting and measuring discards, the number of crew sorting catch, and what steps will be taken to ensure that all catch remains in camera view;

(H) The measurements of all bins, baskets and compartments that will be used to calculate volumetric estimates of weight;

(I) The detailed steps that will be taken to minimize the potential for EM system malfunctions and the steps will be taken, when malfunctions occur, to ensure the adequate monitoring of catch;

(J) The name, address, phone number, and email address of a primary point of contact for vessel operations;

(K) The name, address, and phone number of the vessel's EM service provider, and contact information for a primary point of contact at the EM service provider;

(L) The name, address, phone number, and signature of the applicant, and the date of the application; and,

(M) Any other information required by the EM Program Manager.

(iv) Any updates to information submitted in the initial application, including updates to proposed, self-enforcing agreements, if applicable (*see* paragraph (e)(5)).

(4) *Review of final application.* NMFS may request additional information or revisions from the applicant until NMFS is satisfied that the application is complete. Based on a complete application, if NMFS determines that the applicant has met the requirements of this section, NMFS will issue an IAD and an EM Authorization. If the application is denied, the IAD will provide an explanation of the denial in writing. The applicant may appeal NMFS's determination following the process at § 660.25(g). NMFS will evaluate an application based on the EM Program Guidelines (*see* § 660.600(b)) and the following criteria, at a minimum:

(i) Review of the vessel owner's and operator's eligibility based on the eligibility criteria at paragraph (e)(1);

(ii) Review of the proposed vessel monitoring plan; and,

(iii) Review of the proposed self-enforcing agreement, if applicable.

(5) *Self-enforcing agreement.* In the future, through a proposed and final rulemaking, NMFS may allow for and provide requirements related to the use of voluntary self-enforcing agreements. This agreement would allow a group of eligible vessels to encourage compliance with the requirements of this section through private, contractual arrangements. If such arrangements are used, participating vessel owners must submit the proposed agreement to NMFS for review and acceptance as part of the application process as provided under paragraphs (e)(1) and (3). The existence of a self-enforcing agreement among EM vessels does not foreclose the possibility of independent enforcement action by NMFS OLE or authorized officers.

(f) *Changes to a NMFS-accepted VMP.* A vessel owner may make changes to a NMFS-accepted VMP by submitting a revised plan or plan addendum to NMFS in writing. NMFS will review and accept the change if it meets all the requirements of this section. A vessel monitoring plan addendum must contain:

(1) The date and the name and signature of the vessel owner;

(2) Address, telephone number, fax number and email address of the person submitting the addendum;

(3) A complete description of the proposed VMP change.

(g) *Change in ownership of a vessel.* If a vessel changed ownership, the new owner must apply for a new EM Authorization.

(h) *Effective dates.* The EM Authorization is valid from the effective date until occurrence of one or more of the following:

(1) December 31 if the vessel owner fails to submit a complete renewal form for the following year;

(2) The vessel changes ownership; or,

(3) NMFS notifies the vessel owner that its EM Authorization is invalid. NMFS may invalidate an EM Authorization if NMFS determines that the vessel, vessel owner, and/or operator no longer meets the eligibility criteria specified at paragraph (e)(1). NMFS would first notify the vessel owner of the deficiencies in writing and the vessel owner must correct the deficiencies following the instructions provided. If the deficiencies are not resolved upon review of the first trip following the notification, NMFS will notify the vessel owner in writing that the EM Authorization is invalid and that the vessel is no longer exempt from observer coverage at §§ 660.140(h)(1)(i) and 660.150(j)(1)(i)(B) for that authorization period. The holder may reapply for an EM Authorization for the following authorization period.

(i) *Renewing an EM Authorization.* NMFS will mail EM Authorization renewal forms to existing EM Authorization holders each year on or about: September 1 for non-trawl shorebased IFQ vessels and January 1 for Pacific whiting IFQ and MS/CV vessels. If vessel owners submit completed renewal forms by October 15 for non-trawl shorebased IFQ vessels and February 15 for Pacific whiting IFQ and MS/CV vessels, their EM Authorization will be automatically renewed for the following authorization period.

(j) *EM System Performance Standards.* The specifications (*e.g.,* image resolution, frame rate, user interface) and configuration of an EM system and associated equipment (*e.g.,* number and placement of cameras, lighting) used to meet the requirements of this section must be sufficient to:

(1) Allow easy and complete viewing, identification, and quantification, of catch items discarded at sea, including during low light conditions;

(2) Continuously record vessel location (latitude/longitude coordinates), velocity, course, and sensor data (i.e, hydraulic and winch activity);

(3) Allow the identification of the time, date, and location of a haul/set or discard event;

(4) Record and store image data from all hauls/sets and the duration that fish are onboard the vessel until offloading begins;

(5) Continuously record and store raw sensor data (*i.e.,* GPS and gear sensors) for the entire fishing trip;

(6) Prevent radio frequency interference (RFI) with vessel monitoring systems (VMS) and other equipment;

(7) Allow the vessel operator to test and monitor the functionality of the EM system prior to and during the fishing trip to ensure it is fully functional;

(8) Prevent tampering or, if tampering does occur, show evidence of tampering; and,

(9) Provide image and sensor data in a format that enables their integration for analysis.

(k) *EM data services.* Beginning January 1, 2020, or earlier if notified by NMFS in the **Federal Register** with six months prior notice, a vessel owner with a valid EM Authorization must obtain EM data processing, reporting, and record retention services from a NMFS-permitted EM service provider, as described at § 660.603(m). If the vessel owner changes EM service providers, the vessel owner must ensure the continuity of EM data retention for the entire duration of the required retention period as specified § 660.603(m)(6). NMFS will maintain a list of permitted EM service providers on its Web site.

(l) *EM system operation and maintenance.* The EM system must be recording imagery and sensor data at all times that fish harvested during an EM trip are onboard the vessel until offloading begins. For the purposes of this section, a fully functional EM system is defined as an EM system and associated equipment that meets the performance standards listed in paragraph (k).

(1) *Duties of care.* The operator of a vessel with a valid EM Authorization must maintain the EM system in good working order, including:

(i) Ensuring the EM system is powered continuously during the fishing trip;

(ii) Ensuring the system is functioning for the entire fishing trip and that camera views are unobstructed and clear in quality, such that the performance standards listed in paragraph (j) are met; and,

(iii) Ensuring EM system components are not tampered with, disabled, destroyed, operated or maintained improperly.

(2) *Pre-departure test.* Prior to departing port, the operator of a vessel with a valid EM Authorization must turn the EM system on and conduct a system function test following the instructions from the EM service provider. The vessel operator must verify that the EM system has adequate memory to record the entire trip and that the vessel is carrying one or more spare hard drives with sufficient capacity to record the entire trip.

(3) *EM system malfunctions.* The operator of a vessel with a valid EM Authorization is prohibited from fishing on an EM trip without a fully functional EM system, unless an alternate arrangement has been specified in the NMFS-accepted VMP. In the event of an EM system malfunction, the vessel operator may voluntarily obtain observer coverage and revise the vessel's declaration following the process at § 660.13(d)(5), in which case the vessel operator is no longer exempt from the observer requirements at §§ 660.140(h) and 660.150(j).

(m) *Declaration reports.* The operator of a vessel with a valid EM Authorization must make a declaration report to NMFS OLE prior to leaving port following the process described at § 660.13(d)(5). A declaration report will be valid until another declaration report revising the existing gear or monitoring declaration is received by NMFS OLE. A vessel operator declaring a limited entry midwater trawl, Pacific whiting shorebased IFQ trip or limited entry midwater trawl, Pacific whiting mothership sector (catcher vessel or mothership) trip may only revise the existing monitoring declaration twice during the same calendar year. NMFS may waive this limitation with prior notice if it is determined to be unnecessary for purposes of planning observer deployments. Additional revisions may be made if the EM system has malfunctioned and the vessel operator has chosen to carry an observer, as allowed under paragraph (m)(3); or subsequently, the EM system has been repaired; and upon expiration or invalidation of the vessel's EM Authorization.

(n) *Observer requirements.* The operator of a vessel with a valid EM Authorization must provide advanced notice to NMFS, at least 48 hours prior to departing port, of the vessel operator's intent to take a trip under EM, including: Vessel name, permit number; contact name and telephone number for coordination of observer deployment; date, time, and port of departure; and the vessel's trip plan, including area to be fished and gear type to be used. NMFS may waive this requirement for vessels declared into the Pacific whiting IFQ fishery or mothership sector with prior notice. If NMFS notifies the vessel owner, operator, or manager of any requirement to carry an observer, the vessel may not be used to fish for groundfish without carrying an observer. The vessel operator must comply with the following requirements on a trip that the vessel owner, operator, or manager has been notified is required to carry an observer.

(1) *Notice of departure basic rule.* At least 24 hours (but not more than 36 hours) before departing on a fishing trip, a vessel operator that has been notified by NMFS that his vessel is required to carry an observer, or that is operating in an active sampling unit, must notify NMFS (or its designated agent) of the vessel's intended time of departure. Notice will be given in a form to be specified by NMFS.

(2) *Optional notice—weather delays.* A vessel operator that anticipates a delayed departure due to weather or sea conditions may advise NMFS of the anticipated delay when providing the basic notice described in paragraph (n)(1) of this section. If departure is delayed beyond 36 hours from the time the original notice is given, the vessel operator must provide an additional notice of departure not less than 4 hours prior to departure, in order to enable NMFS to place an observer.

(3) *Optional notice—back-to-back fishing trips.* A vessel operator that intends to make back-to-back fishing trips (*i.e.,* trips with less than 24 hours between offloading from one trip and beginning another), may provide a notice of departure as described in paragraph (n)(1) for both trips, prior to making the first trip. A vessel operator that has given such notice is not required to give additional notice of the second trip.

(4) *Cease fishing report.* Within 24 hours of ceasing the taking and retaining of groundfish, vessel owners, operators, or managers must notify NMFS or its designated agent that fishing has ceased. This requirement applies to any vessel that is required to carry an observer, or that is operating in a segment of the fleet that NMFS has identified as an active sampling unit.

(5) *Waiver.* The West Coast Regional Administrator may provide written notification to the vessel owner stating that a determination has been made to temporarily waive coverage requirements because of circumstances that are deemed to be beyond the vessel's control.

(6) *Accommodations and food.*—(i) Accommodations and food for trips less than 24 hours must be equivalent to those provided for the crew.

(ii) Accommodations and food for trips of 24 hours or more must be equivalent to those provided for the crew and must include berthing space, a space that is intended to be used for sleeping and is provided with installed bunks and mattresses. A mattress or futon on the floor or a cot is not acceptable if a regular bunk is provided to any crew member, unless other arrangements are approved in advance by the Regional Administrator or designee.

(7) *Safe conditions.*—(i) The vessel operator must maintain safe conditions on the vessel for the protection of observers including adherence to all U.S. Coast Guard and other applicable rules, regulations, statutes, and guidelines pertaining to safe operation of the vessel, including, but not limited to rules of the road, vessel stability, emergency drills, emergency equipment, vessel maintenance, vessel general condition and port bar crossings, and provisions at §§ 600.725 and 600.746 of this chapter. An observer may refuse boarding or reboarding a vessel and may request a vessel to return to port if operated in an unsafe manner or if unsafe conditions are identified.

(ii) The vessel operator must have on board a valid Commercial Fishing Vessel Safety Decal that certifies compliance with regulations found in 33 CFR chapter I and 46 CFR chapter I, a certificate of compliance issued pursuant to 46 CFR 28.710 or a valid certificate of inspection pursuant to 46 U.S.C. 3311.

(8) *Observer communications.* The vessel operator must facilitate observer communications by:

(i) Allowing observer(s) to use the vessel's communication equipment and personnel, on request, for the entry, transmission, and receipt of work related messages, at no cost to the observer(s) or the U.S. or designated agent; and

(ii) Ensuring that the vessel's communications equipment, used by observers to enter and transmit data, is fully functional and operational.

(9) *Vessel position.* The vessel operator must allow observer(s) access to the vessel's navigation equipment and personnel, on request, to determine the vessel's position.

(10) *Access.* The vessel operator must allow observer(s) free and unobstructed access to the vessel's bridge, trawl or working deck, holding bins, sorting areas, cargo hold, and any other space that may be used to hold, process, weigh, or store fish at any time.

(11) *Prior notification.* The vessel operator must notify observer(s) at least 15 minutes before fish are brought on board, or fish and fish products are transferred from the vessel, to allow sampling the catch or observing the transfer.

(12) *Records.* The vessel operator must allow observer(s) to inspect and copy any state or federal logbook maintained voluntarily or as required by regulation.

(13) *Assistance.* The vessel operator must provide all other reasonable assistance to enable observer(s) to carry out their duties, including, but not limited to:

(i) Measuring decks, codends, and holding bins.

(ii) Providing a designated safe working area on deck for the observer(s) to collect, sort and store catch samples.

(iii) Collecting samples of catch.

(iv) Collecting and carrying baskets of fish.

(v) Allowing the observer(s) to collect biological data and samples.

(vi) Providing adequate space for storage of biological samples.

(vii) Providing time between hauls to sample and record all catch.

(viii) Sorting retained and discarded catch into quota pound groupings.

(ix) Stowing all catch from a haul before the next haul is brought aboard.

(14) *Sampling station.* To allow the observer to carry out the required duties, the vessel operator must provide an observer sampling station that meets the following requirements so that the observer can carry out required duties.

(i) The observer sampling station must be available to the observer at all times.

(ii) The observer sampling station must be located within 4 m of the location from which the observer samples unsorted catch. Unobstructed passage must be provided between the observer sampling station and the location where the observer collects sample catch. To the extent possible, the area should be free and clear of hazards including, but not limited to, moving fishing gear, stored fishing gear, inclement weather conditions, and open hatches.

(15) *Transfers at sea.* Observers may be transferred at-sea between a MS vessel and a catcher vessel. Transfers at-sea between catcher vessels is prohibited. For transfers, both vessels must:

(i) Ensure that transfers of observers at sea via small boat under its own power are carried out during daylight hours, under safe conditions, and with the agreement of observers involved.

(ii) Notify observers at least 3 hours before observers are transferred, such that the observers can finish any sampling work, collect personal belongings, equipment, and scientific samples.

(iii) Provide a safe pilot ladder and conduct the transfer to ensure the safety of observers during transfers.

(iv) Provide an experienced crew member to assist observers in the small boat in which any transfer is made.

(16) *Housing on vessel in port.* During all periods an observer is housed on a vessel, the vessel operator must ensure that at least one crew member is aboard.

(o) *Inspection.* The operator of a vessel with a valid EM Authorization must make the EM system and associated equipment available for inspection immediately upon request by NMFS OLE personnel, USCG personnel, state enforcement personnel, or any authorized officer.

(p) *Retention requirements.*—(1) *Pacific whiting IFQ and MS/CV vessels.* The operator of a vessel on a declared limited entry midwater trawl, Pacific whiting shorebased IFQ trip or limited entry midwater trawl, Pacific whiting mothership sector (catcher vessel or mothership) trip, EM trip must retain all fish until landing, with exceptions listed below.

(i) Minor operational discards are permitted. Minor operational discards include mutilated fish; fish vented from an overfull codend, fish spilled from the codend during preparation for transfer to the mothership; and fish removed from the deck and fishing gear during cleaning. Minor operational discards do not include discards that result when more catch is taken than is necessary to fill the hold or catch from a tow that is not delivered.

(ii) Large individual marine organisms (*i.e.,* all marine mammals, sea turtles, and seabirds, and fish species longer than 6 ft (1.8 m) in length) may be discarded.

(iii) Crabs, starfish, coral, sponges, and other invertebrates may be discarded.

(iv) Trash, mud, rocks, and other inorganic debris may be discarded.

(iv) A discard that is the result of an event that is beyond the control of the vessel operator or crew, such as a safety issue or mechanical failure, is permitted.

(2) *Non-trawl shorebased IFQ.* A vessel operator on a declared limited entry groundfish non-trawl, shorebased IFQ trip must retain all IFQ species (as defined at § 660.140(c)), salmon, and non-IFQ rockfish, flatfish, and roundfish, with exceptions listed below. The operator of a non-trawl shorebased IFQ vessel must discard Pacific halibut, Dungeness crab caught seaward of Washington or Oregon, green sturgeon, eulachon, seabirds, sea turtles, and marine mammals.

(i) Mutilated and depredated fish may be discarded.

(ii) Crabs, starfish, coral, sponges, and other invertebrates may be discarded.

(iii) Trash, mud, rocks, and other inorganic debris may be discarded.

(iv) A discard that is the result of an event that is beyond the control of the vessel operator or crew, such as a safety issue or mechanical failure, is permitted.

(q) *Changes to retention requirements.* Retention requirements for non-trawl shorebased IFQ vessels have been designated as "routine," which means that they can be changed after a single Council meeting following the procedures described at § 660.60(c).

(r) *Catch handling.* The vessel operator of a vessel on an EM trip must ensure that all catch is handled in a manner that enables the EM system to record it and that is consistent with the specific catch handling instructions in the NMFS-accepted VMP.

(s) *Reporting requirements.*—(1) *Discard logbook.* The operator of a vessel with a valid EM Authorization must complete, submit, and maintain onboard the vessel an accurate federal discard logbook for each EM trip on forms supplied by or approved by NMFS. If authorized in writing by the NMFS, a vessel owner or operator may submit reports electronically, for example by using a VMS or other media. A state logbook that contains all the required information may be submitted in place of a federal discard logbook. If operating an MS/CV vessel, the vessel operator must provide logbook information to the mothership observer by transmitting the logbook information via radio or email to the mothership at the completion of each haul.

(2) *Submission of logbooks.* Vessel operators must submit copies of the federal discard logbook and state retained logbook to NMFS or its agent within 24-hours of the end of each EM trip.

(3) *Submission of hard drives.* Vessel operators must submit hard drives to NMFS or its agent using a method that requires a signature for delivery and provides a return receipt or delivery notification to the sender. Beginning January 1, 2020, or earlier if announced by NMFS in the **Federal Register** with six months prior notice, a vessel operator must submit hard drives to the vessel owner's contracted EM service provider. Deadlines for submission are as follows:

(i) *Pacific whiting IFQ vessels.* Hard drives containing data from an EM trip must be postmarked within 10 calendar days of the end of that EM trip.

(ii) *Mothership catcher vessels.* Hard drives containing data from an EM trip must be postmarked within 24-hours of the catcher vessel's return to port.

(iii) *Non-trawl shorebased IFQ vessels.* Hard drives containing data from an EM trip must be postmarked within 10 calendar days of the end of that EM trip.

(t) *Retention of records.* The operator of a vessel with a valid EM Authorization must maintain federal discard logbooks onboard the vessel until the end of the fishing year during which the EM trips were conducted, and make the report forms available to observers, NMFS staff, or authorized officers, immediately upon request. The vessel owner must maintain the federal discard logbooks and other records specified in this section, or used in the preparation of records or reports specified in this section or corrections to these reports, for a period of not less than three years after the date of landing from an EM trip. The vessel owner must make such records available for inspection by NMFS staff or authorized officers, immediately upon request.

(u) *First receiver requirements.* (1) *Prohibited species handling and disposition.* To ensure compliance with fishery regulations at 50 CFR part 300, subparts E and F, and part 600, subpart H; with the Pacific Salmon Fishery Management Plan; and with the Pacific Halibut Catch Share Plan; the handling and disposition of all prohibited species in EM trip landings are the responsibility of the first receiver and must be consistent with the following requirements:

(i) Any prohibited species landed at first receivers must not be transferred, processed, or mixed with another landing until the catch monitor has: Recorded the number and weight of salmon by species; inspected all prohibited species for tags or marks; and, collected biological data, specimens, and genetic samples.

(ii) No part of any prohibited species may be retained for personal use by a vessel owner or crew member, or by a first receiver or processing crew member. No part of any prohibited species may be allowed to reach commercial markets.

(iii) Prohibited species suitable for human consumption at landing must be handled and stored to preserve the quality. Priority in disposition must be given to the donation to surplus food collection and distribution system operated and established to assist in bringing donated food to nonprofit charitable organizations and individuals for the purpose of reducing hunger and meeting nutritional needs.

(iv) The first receiver must report all prohibited species landings on the electronic fish ticket and is responsible for maintaining records verifying the disposition of prohibited species. Records on catch disposition may include, but are not limited to: Receipts from charitable organizations that include the organization's name and amount of catch donated; cargo manifests setting forth the origin, weight, and destination of all prohibited species; or disposal receipts identifying the recipient organization and amount disposed. Any such records must be maintained for a period not less than three years after the date of disposal and such records must be provided to NMFS OLE immediately upon request.

(2) *Protected Species handling and disposition.* All protected species must be abandoned to NMFS or the US Fish and Wildlife Service or disposed of consistent with paragraphs (u)(2)(i) and (ii) of this section. No part of any protected species may be retained for personal use by a vessel owner or crew member, or by a first receiver or processing crew member. No part of any protected species may be allowed to reach commercial markets.

(i) *Eulachon and green sturgeon.* Must be sorted and reported by species on electronic fish tickets and state landing receipts and may not be reported in unspecified categories. Whole body specimens of green sturgeon must be retained, frozen, stored separately by delivery, and labeled with the vessel name, electronic fish ticket number, and date of landing. Arrangements for transferring the specimens must be made by contacting NMFS Southwest Fisheries Science Center at 831–420–3903 within 72 hours after the completion of the offload.

(ii) *Seabirds, marine mammals, and sea turtles.* Albatross must reported to the U.S. Fish and Wildlife Service 541–867–4558 extension 237 or 503–231–6179) as soon as possible and directions for surrendering must be followed. Marine mammals and sea turtles must be reported to NMFS as soon as possible (206–526–6550) and directions for surrendering or disposal must be followed. Whole body specimens must labeled with the vessel name, electronic fish ticket number, and date of landing. Whole body specimens must be kept frozen or on ice until arrangements for surrendering or disposing are completed. Unless directed otherwise, after reporting is completed, seabirds, marine mammals, and sea turtles may be disposed by incinerating, rendering, composting, or returning the carcasses to sea.

[FR Doc. 2016–21058 Filed 9–2–16; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 81, No. 172
Tuesday, September 6, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Re-Establishment of and Notice for Solicitation for the Council for Native American Farming and Ranching

AGENCY: Office of the Secretary, USDA.

ACTION: Notice of amended call for nominations.

SUMMARY: The USDA announces that it is extending the solicitation period for applications published in notice FR Doc. 2016–16099 for individuals to be considered for membership. Candidates who wish to be apply and be considered on the Council for Native American Farmers and Ranchers must submit an AD–755 application form and resume to the Secretary of Agriculture. Cover letters should be addressed to the Secretary of Agriculture. The application form can be found at: *http://www.usda.gov/documents/OCIO_AD_755_Master_2012.pdf.*

DATES: Submit nominations on or before September 22, 2016.

ADDRESSES: All nomination materials should be mailed in a single, complete package and postmarked by 45 days of this announcement. All nominations for membership should be sent to: Thomas Vilsack, Secretary, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250, Attn: Office of Tribal Relations. Send comments to the Office of Tribal Relations, 500A Whitten Building, 1400 Independence Avenue SW., Washington DC 20250.

FOR FURTHER INFORMATION CONTACT: Josiah Griffin, Acting Designated Federal Officer, Council for Native American Farming and Ranching. Email your questions to Josiah Griffin at *tribal.relations@osec.usda.gov* or call 202–205–2249.

SUPPLEMENTARY INFORMATION: In accordance with the provisions of the Federal Advisory Council Act (FACA) as amended (5 U.S.C. App. 2) and with the concurrence of the General Services Administration, the Department of Agriculture (USDA) is announcing the re-establishment of the advisory Council for Native American Farmers and Ranchers (Council). The Council is a discretionary advisory committee that operates under the provisions of the FACA and reports to the Secretary of Agriculture. The purpose of this Council is: (1) To advise the Secretary of Agriculture on issues related to the participation of Native American farmers and ranchers in USDA programs; (2) to transmit recommendations concerning any changes to regulations or internal guidance or other measures that would eliminate barriers to program participation for Native American farmers and ranchers; (3) to examine methods of maximizing the number of new farming and ranching opportunities created through enhanced extension, sound conservation practices, targeted rural business services, and financial literacy services; (4) to examine methods of encouraging intergovernmental cooperation to mitigate the effects of land tenure and probate issues on the delivery of USDA programs; (5) to evaluate other methods of creating new farming or ranching opportunities for Native American producers; and (6) to address other Native American related issues as deemed appropriate.

The Council has 15 members, 11 of whom will be Native American leaders or persons who represent the interests of Native American tribes or Native American organizations. The term "Native American leaders" is not limited to elected Tribal representatives or members or persons with Native American ancestry. The remaining four members are the following high-ranking USDA officials: (1) Director, Office of Tribal Relations; (2) Administrator, Farm Service Agency; (3) Chief, Natural Resources and Conservation Services; and (4) Assistant Secretary, Office of the Assistant Secretary for Civil Rights.

Members serve without compensation, but may receive reimbursement for travel expenses and per diem in accordance with USDA travel regulations for attendance at Council functions. Council members who represent the interests of Native American farmers and ranchers may also be paid an amount not less than $100 per day for time spent away from their employment or farming or ranching operation, subject to the availability of funds. Members may include:

(1) Native American farmers or ranchers who have participated in USDA loan, grant, conservation, or payment programs;

(2) Representatives of organizations with a history of working with Native American farmers or ranchers;

(3) Representatives of tribal governments with demonstrated experience working with Native American farmers or ranchers; and

(4) Such other persons as the Secretary considers appropriate.

The Secretary of Agriculture invites those individuals, organizations, and groups affiliated with the categories listed above or who have knowledge of issues related to the purpose of the Council to nominate individuals for membership on the Council. Individuals and organizations who wish to nominate experts for this or any other USDA advisory committee should submit a letter to the Secretary listing these individuals' names and business address, phone, and email contact information. The Secretary of Agriculture seeks a diverse group of members representing a broad spectrum of persons interested in providing suggestions and ideas on how USDA can tailor its farm programs to meet the needs of Native American farmers and ranchers. Individuals receiving nominations will be contacted and asked to return the AD–755 application form and a resume within 10 business days of notification. All candidates will be vetted and considered for appointment by the Secretary of Agriculture. Equal opportunity practices will be followed in all appointments to the Council in accordance with USDA policies. The Council will meet at least once per fiscal year.

Dated: August 29, 2016.

Sedelta Oosahwee,

Acting Director.

[FR Doc. 2016–21280 Filed 9–2–16; 8:45 am]

BILLING CODE 3410–01–P

DEPARTMENT OF AGRICULTURE

Forest Service

Eastern Washington Cascades Provincial Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Eastern Washington Cascades Provincial Advisory Committee (PAC) will meet in Wenatchee, Washington. The committee is authorized pursuant to the implementation of E–19 of the Record of Decision and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to provide advice and make recommendations to promote a better integration of forest management activities between Federal and non-Federal entities to ensure that such activities are complementary. PAC information can be found at the following Web site: *http://www.fs.usda.gov/main/okawen/workingtogether/advisorycommittees.*

DATES: The meeting will be held on Wednesday, September 28, 2016, from 9 a.m. to 3 p.m.

All PAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: The meeting will be held at the Okanogan-Wenatchee National Forest (NF) Headquarters Office, 215 Melody Lane, Wenatchee, Washington.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Okanogan-Wenatchee NF Headquarters Office. Please call ahead at 509–664–9292 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Robin DeMario, PAC Coordinator by phone at 509–664–9292, or by email at *rdemario@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to update members on the:

1. Year end accomplishments and key project plans for Fiscal Year 2016,
2. I–90 Wildlife Project,
3. Yakima Basin Integrated Plan, and
4. Strategic prioritization of watershed restoration projects.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by September 21, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to Robin DeMario, PAC Coordinator, 216 Melody Lane, Wenatchee, Washington 98801; or by email to *rdemario@fs.fed.us,* or via facsimile to 509–664–9286.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: August 30, 2016.

Michael R. Williams,

Forest Supervisor, Okanogan-Wenatchee National Forest.

[FR Doc. 2016–21302 Filed 9–2–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Medicine Bow-Routt National Forest and Thunder Basin National Grassland; Routt County, Colorado; Steamboat Ski Resort, Steamboat EIS

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The United States Forest Service (Forest Service), Medicine Bow-Routt National Forests and Thunder Basin National Grassland (MBRTB), is preparing an Environmental Impact Statement (EIS) to consider and disclose the anticipated environmental effects of implementing projects proposed by Steamboat Ski and Resort Corporation (SSRC) at Steamboat Ski Resort (Steamboat). The proposal would occur within the resort's existing Special Use Permit area (Permit Boundary) that is located on National Forest System (NFS) lands, and would be consistent with the 2011 Steamboat Master Development Plan Amendment (MDPA). These projects are proposed to improve the quality of guest services, increase operational efficiencies, and enhance the recreation experience for all skier ability levels.

DATES: Comments concerning the scope of the analysis must be received by September 19, 2016. A public open house regarding this proposal will be held at the Steamboat Springs Community Center located at 1605 Lincoln Avenue, Steamboat Springs, CO 80427 on August 25th, 2016 from 5:00pm to 7:00pm. The draft environmental impact statement is expected to be available for public review in January 2017, and the final environmental impact statement is expected September 2017.

ADDRESSES: Send written comments to: Dennis Jaeger, Forest Supervisor, c/o Erica Dickerman, Project Leader, Medicine Bow-Routt National Forests and Thunder Basin National Grassland; 2468 Jackson Street, Laramie, WY 82070; FAX (307) 745–2398 or by email to: *comments-rocky-mountain-medicine-bow-routt@fs.fed.us* (please include "Steamboat EIS" in the subject line). Electronic comments must be submitted in Word (.doc), Rich Text (.rtf), or Adobe Acrobat (.pdf) format.

FOR FURTHER INFORMATION CONTACT: Additional information related to the proposed project can be obtained from: Erica Dickerman, Recreation Specialist, Hahns Peak Bears Ears Ranger District, who can be reached by phone at (970) 870–2185 or by email at *edickerman@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The purpose and need for the action is to: improve the teaching terrain for beginner ability level guests to provide for an effective and comfortable learning progression; address operational inefficiencies and circulation of existing terrain; and provide additional lift-served terrain to meet guest expectations for diverse terrain offerings.

Proposed Action

The proposed action consists of the following specific projects:

Rough Rider and Bashor Bowl

Creation of the Rough Rider Learning Center would include installation of a gondola (Bashor Gondola, located on private lands), construction of the Bashor Children's Facility and Restaurant (located on private lands), removal of the existing Bashor Pavilion and bathroom facilities, installation of multiple moving carpet lifts, installation of a fixed grip chairlift (Rough Rider lift), removal of the existing Rough Rider platter lift, construction of a new skier bypass from *Boulevard* to the Rough Rider Learning Center, re-grading of associated novice and beginner terrain, and installation of snowmaking infrastructure.

Proposed improvements within Bashor Bowl include replacement and realignment of the outdated Bashor lift (located on both private and NFS lands), construction of two new skiways from the realigned Bashor lift top terminal, grading at the base of Bashor Bowl, expansion of the Rabbit Ears Terrain Park, removal of the Mavericks Superpipe, construction of a new novice trail connecting *Yoo Hoo* to *Big Foot*, and reconfiguration of existing snowmaking infrastructure.

Pony Express

Proposed improvements within the Pony Express area include: Enhancements to trail corridors through vegetation removal, grading, and rock blasting; increased capacity of the Pony Express lift by adding carriers to the existing lift; construction of a ski patrol and restroom facility near the top terminal of the Pony Express lift; installation of winch cat anchors; construction of a ski-way from the junction of *Lower Middle Rib* and *Chaps* ski trails to the Storm Peak Express chairlift; and installation of snowmaking infrastructure and coverage to *Upper* and *Lower Middle Rib, the Crux, Upper* and *Lower Longhorn,* Lower Pony Express lift line, *Upper* and *Lower Storm Peak Express Connectors, BC Ski Way,* and *Chaps.*

Pioneer Ridge

Steamboat proposes to expand the operational boundary by approximately 355 acres to encompass Pioneer Ridge, construct a new detachable quad chair lift (Pioneer 2 lift), create 95 acres of gladed skiing, conduct 40 acres of hazard tree removal and vegetation management, install a bridge over Burgess Creek and construct an associated collector skiway, and define multiple gladed trails and egress routes to connect with existing and proposed terrain and facilities.

Responsible Official

The Responsible Official is Dennis Jaeger, Forest Supervisor for the MBRTB.

Nature of Decision To Be Made

Based on the analysis that will be documented in the forthcoming EIS, the Responsible Official will decide whether or not to implement, in whole or in part, the Proposed Action or another alternative that may be developed by the Forest Service as a result of scoping. The Responsible Official will also decide what, if any, mitigation measures, and monitoring requirements should be made part of the decision.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. The Forest Service is soliciting comments from Federal, State and local agencies and other individuals or organizations that may be interested in or affected by implementation of the proposed projects. A public open house for this proposal will be held at the Steamboat Springs Community Center located at 1605 Lincoln Avenue, Steamboat Springs, CO 80427 on August 25 from 5:00 p.m. to 7:00 p.m. Representatives from the MBRTB, Hahns Peak Bears Ears Ranger District, and SSRC will be present to answer questions and provide additional project information.

To be most helpful, comments should be specific to the project area and should identify resources or effects that should be considered by the Forest Service. Submitting timely, specific written comments during this scoping period or any other official comment period establishes standing for filing objections under 36 CFR 218 subparts A and B. Additional information and maps of this proposal can be found at: *http://www.fs.usda.gov/project/?project=48246.*

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered.

Dated: August 10, 2016.

Carolyn Upton,

Acting Forest Supervisor.

[FR Doc. 2016–21236 Filed 9–2–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

U.S. Census Bureau

Proposed Information Collection; Comment Request; 2016–2018 Business R&D and Innovation Surveys

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: To ensure consideration, written or on-line comments must be submitted on or before November 7, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *jjessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Michael Flaherty, U.S. Census Bureau, HQ–6H149, 4600 Silver Hill Rd., Suitland, MD 20746 (301) 763–7699 (or via the internet at *michael.j.flaherty@census.gov*).

SUPPLEMENTARY INFORMATION:

I. Abstract

The U.S. Census Bureau, with support from the National Science Foundation (NSF), plans to conduct the Business R&D and Innovation Survey (BRDIS) for the 2016–2018 survey years. The BRDIS covers all domestic, non-farm, for-profit businesses with at least one paid employee. The BRDIS provides the only comprehensive data on research and development costs and detailed expenses by type and industry.

The Census Bureau has conducted an R&D survey since 1957 (the Survey of Industrial Research and Development (SIRD) from 1957–2007 and BRDIS from 2008–present), collecting primarily financial information on the systematic work companies undertake to discover new knowledge or use existing knowledge to develop new or improved goods and services.

Prior to 2016, only companies with a minimum of five employees were in scope to the BRDIS. Beginning in 2016, the BRDIS will increase it's scope to include microbusinesses, or firms with fewer than five employees. Sampled companies in this target population will receive a BRDI–M form. Companies with five or more employees will receive the standard form (BRDI–1) or if selected for the screener questionnaire, the BRDI–1(S) form. Expanding the coverage of the BRDIS will help policymakers address issues such as how small businesses are affected by the rapid changes in our economy and what the smallest businesses are doing to be competitive.

The 2016–2018 BRDIS will continue to collect the following types of information:

- R&D expense based on accepted accounting standards.
- Worldwide R&D of domestic companies.
- Business segment detail.
- R&D-related capital expenditures.
- Detailed data about the R&D workforce.
- R&D strategy and data on the potential impact of R&D on the market.
- R&D directed to application areas of particular national interest.
- Data measuring innovation, intellectual property protection activities and technology transfer.

The BRDI–1 form utilizes a booklet instrument that facilitates the collection of information from various contacts within each company who have the best understanding of the concepts and definitions being presented as well as access to the information necessary to provide the most accurate response. The sections of the booklet correspond to areas within the company and currently include: A company information section that includes detailed innovation questions; a financial section focused on company R&D expenses; a human resources section; an R&D strategy and management section; an IP and technology transfer section; and a section focused on R&D that is funded or paid for by third parties. A web instrument is also available to respondents. The web instrument for the BRDI–1 form incorporates Excel spreadsheets that are provided to facilitate the electronic collection of information from various areas of the companies. Respondents have the capability to download the spreadsheets from the Census Bureau's Web site. A consolidator spreadsheet is also available to assist companies that need to gather information from business units and then compile the information into one company report.

Domestic and foreign researchers in academia, business, and government analyze and cite data from the BRDIS. Among the federal government users are the Bureau of Economic Analysis (BEA) and the White House's Office of Science and Technology Policy (OSTP). BEA includes R&D in the system of national accounts that measures the economic well-being of the country. BRDIS data are key inputs into these accounts, which feed into the calculation of the U.S. Gross Domestic Product (GDP). The White House, in 2006, issued the American Competitiveness Initiative to "increase investments in research and development, strengthen education, and encourage entrepreneurship." In support of this initiative and in response to legislative mandates, data on R&D are delivered to OSTP, primarily in the biennial National Science Board report Science and Engineering Indicators. Also, the National Science Foundation (NSF) produces a series of publications containing R&D data including the National Patterns of R&D Resources series, the S&E State Profile series, and the annual Business R&D and Innovation series. Special reports and other publications are also prepared.

II. Method of Collection

The Census Bureau will use a paperless strategy for the standard form (BRDI–1). Respondents will be mailed a letter referring them to the Census Bureau's Business Help Site where they can report online. Some companies selected for the screener form [BRDI–1(S)] will receive a letter only in initial mail out, directing them to report online. Others will receive a paper form in initial mailout that they can mail back. The microbusiness form (BRDI–M) is a mail out/mail back survey form. Respondents to all form types will have the option to report electronically. The due date for the standard form will be approximately 60 days from receipt. The due date for all other form types will be approximately 30 days from receipt.

III. Data

OMB Control Number: 0607–0912.

Form Number: BRDI–1, BRDI–1(S), and BRDI–M.

Type of Review: Regular submission.

Affected Public: All domestic, non-farm, for-profit (public or private) businesses with at least one paid employee.

Estimated Number of Respondents:

BRDI–1—(Standard Form)	7,000
BRDI–1(S)—(Screener Form)	38,000
BRDI–M—(Microbusiness Form)	200,000
Total	245,000

Estimated Time per Response:

BRDI–1—(Standard Form)	14.85 hours.
BRDI–1(S)—(Screener Form)	0.59 hours.
BRDI–M—(Microbusiness Form).	0.25 hours.

Estimated Total Annual Burden Hours: 176,370.

Estimated Total Annual Cost: $0.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13, United States Code, Sections 8(b), 131, and 182, and Title 42, United States Code, Sections 1861–76 (National Science Foundation Act of 1950, as amended).

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: August 31, 2016

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2016–21281 Filed 9–2–16; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–30–2016]

Foreign-Trade Zone (FTZ) 125—South Bend, Indiana; Authorization of Proposed Production Activity; LionsHead Specialty Tire & Wheel, LLC (Wheel Assemblies for Specialty Applications); Goshen, Indiana

On May 3, 2016, LionsHead Specialty Tire & Wheel, LLC, submitted a notification of proposed production activity to the Foreign-Trade Zones (FTZ) Board for its facility within FTZ 125—Site 3, in Goshen, Indiana.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (81 FR 29527–29528, May 12, 2016). The FTZ Board has determined that no further review of the activity is warranted at this time. The production activity described in the notification is authorized, subject to the FTZ Act and the Board's regulations, including Section 400.14.

Dated: August 31, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–21342 Filed 9–2–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–33–2016]

Foreign-Trade Zone (FTZ) 281—Miami, Florida; Authorization of Production Activity; Alpha Marketing Network, Inc. d/b/a AMN Distributors (Kitting-Wine Gift Sets); Miami, Florida

On May 3, 2016, Miami-Dade County, grantee of FTZ 281, submitted a notification of proposed production activity to the FTZ Board on behalf of Alpha Marketing Network, Inc. d/b/a AMN Distributors, within Site 41 in Miami, Florida.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (81 FR 30517, May 17, 2016). The FTZ Board has determined that no further review of the activity is warranted at this time. The production activity described in the notification is authorized, subject to the FTZ Act and the Board's regulations, including Section 400.14.

Dated: August 30, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–21339 Filed 9–2–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–045]

1-Hydroxyethylidene-1, 1-Diphosphonic Acid From People's Republic of China: Postponement of Preliminary Determination of Antidumping Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Effective September 6, 2016.

FOR FURTHER INFORMATION CONTACT: Omar Qureshi or Kenneth Hawkins, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5307, or (202) 482–6491, respectively.

SUPPLEMENTARY INFORMATION:

Postponement of Preliminary Determination

On April 20, 2016, the Department of Commerce ("Department") initiated an antidumping duty investigation of 1-hydroxyethylidene-1, 1-diphosphonic acid from the People's Republic of China.[1] Section 733(b)(1)(A) of the Tariff Act of 1930, as amended ("the Act"), and 19 CFR 351.205(b)(1) state that the Department will make a preliminary determination no later than 140 days after the date of the initiation (*i.e.,* April 20, 2016). Accordingly, the preliminary determination of this antidumping duty investigation is currently due no later than September 7, 2016.

Sections 733(c)(1)(B)(i) and (ii) of the Act permit the Department to postpone the time limit for the preliminary determination if it concludes that the parties concerned are cooperating and determines that the case is extraordinarily complicated by reason of the number and complexity of the transactions to be investigated or adjustments to be considered, the novelty of the issues presented, or the number of firms whose activities must be investigated, and additional time is necessary to make the preliminary determination. Under this section of the Act, the Department may postpone the preliminary determination until no later than 190 days after the date on which the Department initiated the investigation.

The Department determines that the parties concerned are cooperating and that the case is extraordinarily complicated. Additional time is necessary to issue and analyze supplemental questionnaires and to make a preliminary determination in this investigation.

Therefore, in accordance with section 733(c)(1)(B) of the Act, the Department is postponing the deadline for the preliminary determination by 50 days, to October 27, 2016. In accordance with section 735(a)(1) of the Act, the deadline for the final determination of this investigation will continue to be 75 days after the date of the preliminary determination, unless postponed at a later date.

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f)(1).[2]

Dated: August 30, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–21331 Filed 9–2–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–821–811]

Solid Fertilizer Grade Ammonium Nitrate From the Russian Federation: Rescission of Antidumping Duty Administrative Review; 2015–2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is rescinding the administrative review of the antidumping duty order on solid fertilizer grade ammonium nitrate (ammonium nitrate) from the Russian Federation (Russia). The review covers the following producers/exporters of the subject merchandise: (1) JSC Acron/JSC Dorogobuzh (collectively, "Acron") and (2) MCC EuroChem and its affiliates OJSC NAK Azot and OJSC Nevinnomyssky Azot (collectively, "EuroChem"). The period of review (POR) is April 1, 2015, through March 31, 2016.

DATES: Effective September 6, 2016.

FOR FURTHER INFORMATION CONTACT: David Crespo, AD/CVD Operations, Office II, Enforcement and Compliance,

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[1] *See 1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 81 FR 25377 (April 28, 2016).

[2] We acknowledge that the Department inadvertently did not notify the parties to this investigation of this postponement within the time frame provided in section 733(c)(2) of the Act and 19 CFR 351.205(f)(1).

International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3693.

Background

On April 28, 2016, the Department received a timely request, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), from CF Industries, Inc. and El Dorado Chemical Company (collectively, petitioners) to conduct an administrative review of the sales of Acron and EuroChem.[1] On June 6, 2016, the Department published in the **Federal Register** a notice of initiation of an administrative review of the antidumping duty order on ammonium nitrate from Russia with respect to Acron and EuroChem.[2] On June 30, 2016, the Department received a timely notice from Acron notifying the Department that it had no shipments of subject merchandise to the United States during the POR.[3] On August 18, 2016, the petitioners withdrew their request for an administrative review with respect to Acron and EuroChem.[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if a party that requested the review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review. The petitioners withdrew their request for review by the 90-day deadline, and no other party requested an administrative review of the antidumping duty order on ammonium nitrate from Russia for the POR. Accordingly, the Department is rescinding the administrative review of the antidumping order on ammonium nitrate from Russia covering the period April 1, 2015 through March 31, 2016.

Assessment

The Department will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions directly to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as the only reminder to importers of their responsibility, under 19 CFR 351.402(f)(2), to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement may result in the presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This notice is issued and published in accordance with section 751 of the Act and 19 CFR 351.213(d)(4).

Dated: August 26, 2016.

Gary Tavernman,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–21332 Filed 9–2–16; 8:45 am]

BILLING CODE 3510–DS–P

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[1] *See* the letter from the petitioners to the Department, entitled, "Ammonium Nitrate from the Russian Federation: Request for Review," dated April 28, 2016.

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 81 FR 36268 (June 6, 2016).

[3] *See* the letter from Acron to the Department, entitled, "Solid Fertilizer Grade Ammonium Nitrate from the Russian Federation: No Shipment Letter," dated June 30, 2016.

[4] *See* the letter from the petitioners to the Department, entitled, "Ammonium Nitrate from the Russian Federation: Withdrawal of Request for Administrative Review," dated August 18, 2016.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–040]

Truck and Bus Tires From the People's Republic of China: Preliminary Affirmative Determinations of Sales at Less Than Fair Value and Critical Circumstances, and Postponement of Final Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) preliminarily determines that imports of truck and bus tires from the People's Republic of China (the PRC) are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is July 1, 2015, through December 31, 2015. The estimated margins of sales at LTFV are shown in the "Preliminary Determination" section of this notice. Interested parties are invited to comment on this preliminary determination.

DATES: Effective September 6, 2016.

FOR FURTHER INFORMATION CONTACT: Yang Jin Chun or Andre Gziryan, AD/CVD Operations Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5760 and (202) 482–2201, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department initiated this investigation on February 18, 2016.[1] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum dated concurrently with and hereby adopted by this notice.[2] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and to all parties in the Department's Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/.*

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[1] *See Truck and Bus Tires From the People's Republic of China: Initiation of Antidumping Duty Investigation,* 81 FR 9434 (February 25, 2016) (*Initiation Notice*).

[2] *See* Memorandum from Associate Deputy Assistant Secretary Gary Taverman to Assistant Secretary Paul Piquado entitled, "Truck and Bus Tires from the People's Republic of China: Decision Memorandum for Preliminary Affirmative Determinations of Sales at Less Than Fair Value and Critical Circumstances, and Postponement of Final Determination" dated concurrently with and hereby adopted by this notice (Preliminary Decision Memorandum).

Scope of the Investigation

The products covered by this investigation are truck and bus tires. For a full description of the scope of this investigation, *see* the "Scope of the Investigation" in Appendix I of this notice.

Scope Comments

In accordance with the *Preamble* to the Department's regulations,[3] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[4] Certain interested parties commented on the scope of the investigation, as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record, and an accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum issued concurrently with this notice.[5]

Postponement of Deadline for the Preliminary Determination

The Department published the notice of postponement of preliminary determination of this investigation on June 2, 2016.[6] Pursuant to sections 733(c)(1)(B)(i) and (ii) of the Tariff Act of 1930, as amended (the Act), we postponed the preliminary determination by 50 days.[7] As a result of the postponement, the deadline for the preliminary determination of this investigation is August 26, 2016.

Methodology

The Department is conducting this investigation in accordance with section 731 of the Act. We calculated export prices in accordance with section 772 of the Act. Because the PRC is a non-market economy, within the meaning of section 771(18) of the Act, we calculated normal value (NV) in accordance with section 773(c) of the Act. For a full discussion of the Department's methodology, *see* the Preliminary Decision Memorandum.

Affirmative Preliminary Determination of Critical Circumstances

On August 2, 2016, in accordance with section 733(e)(1) of the Act and 19 CFR 351.206, the petitioner[8] timely filed an allegation that critical circumstances exist with respect to all imports of truck and bus tires from the PRC.[9] We preliminarily determine that critical circumstances exist for mandatory respondent Prinx Chengshan (Shandong) Tire Co., Ltd. (PCT), the non-selected separate rate respondents, and the PRC-wide entity.[10]

Combination Rates

In the *Initiation Notice,* the Department stated that it would calculate combination rates for the respondents that are eligible for a separate rate in this investigation.[11] Policy Bulletin 05.1 describes this practice.[12]

Preliminary Determination

The Department preliminarily determines that the following weighted-average dumping margins exist:

Exporter	Producer	Weighted average margin (%)
Prinx Chengshan (Shandong) Tire Co., Ltd	Prinx Chengshan (Shandong) Tire Co., Ltd	20.87
Actyon Tyre Resources Co., Limited	Chao Yang Long March Tyre Co., Ltd	20.87
Actyon Tyre Resources Co., Limited	Shandong Haohua Tires Co., Ltd	20.87
Actyon Tyre Resources Co., Limited	Shandong Longyue Rubber Co., Ltd	20.87
Aosen Tire Co., Ltd	Qingdao Taifa Group Co., Ltd	20.87
Aosen Tire Co., Ltd	Shandong Chuanghua Tire Co., Ltd	20.87
Aosen Tire Co., Ltd	Shandong Hawk International Rubber Industry Co., Ltd	20.87
Aosen Tire Co., Ltd	Shandong Hugerubber Co., Ltd	20.87
Aosen Tire Co., Ltd	Shandong Yongsheng Rubber Group Co., Ltd	20.87
Aosen Tire Co., Ltd	Shandong Zhentai Group Co., Ltd	20.87
Beijing BOE Commerce Co., Ltd	China National Tyre & Rubber Guilin Co., Ltd	20.87
Beijing BOE Commerce Co., Ltd	Shandong Hawk International Rubber Industry Co., Ltd	20.87
Best Choice International Trade Co., Ltd	Aeolus Tyre Co., Ltd	20.87
Best Choice International Trade Co., Ltd	Qingdao Yellow Sea Rubber Co., Ltd	20.87
Best Choice International Trade Co., Ltd	Shan Dong Kaixuan Rubber Co., Ltd	20.87
Best Choice International Trade Co., Ltd	Sichuan Kalevei Technology Co., Ltd	20.87
Best Choice International Trade Co., Ltd	ZC Rubber Group Co., Ltd	20.87
Bestyre International Industrial Limited	Chaoyang Long March Tyre Co., Ltd	20.87
Bestyre International Industrial Limited	Chaoyang Long March Tyre New Co., Ltd	20.87
BOE Commerce Co., Ltd	Aeolus Tyre Co., Ltd	20.87
BOE Commerce Co., Ltd	China National Tyre & Rubber Guilin Co., Ltd	20.87
BOE Commerce Co., Ltd	Shandong Anchi Tyres Co., Ltd	20.87
BOE Commerce Co., Ltd	Shandong Hawk International Rubber Industry Co., Ltd	20.87
BOE Commerce Co., Ltd	Shandong Hengyu Rubber Co., Ltd	20.87
BOE Commerce Co., Ltd	Shandong Hengyu Science & Technology Co., Ltd	20.87
BOE Commerce Co., Ltd	Shandong Jinyu Tyre Co., Ltd	20.87
BOE Commerce Co., Ltd	Zhucheng Guoxin Rubber Co., Ltd	20.87
Briway Tire Co., Ltd	Shandong Kaixuan Rubber Co., Ltd	20.87

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[3] *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

[4] *See Initiation Notice,* 81 FR at 9435.

[5] *See* Memorandum entitled "Truck and Bus Tires from the People's Republic of China: Preliminary Scope Decision Memorandum," dated concurrently with this notice (Preliminary Scope Decision Memorandum).

[6] *See Truck and Bus Tires from the People's Republic of China: Postponement of Preliminary Determinations of Antidumping Duty Investigation,* 81 FR 35332 (June 2, 2016).

[7] *Id.*

[8] United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO–CLC (the petitioner).

[9] *See* Letter from the petitioner, "Truck and Bus from the People's Republic of China (A–570–040): Petitioner's Critical Circumstances Allegation," dated August 2, 2016.

[10] *See* Preliminary Decision Memorandum at 5–9.

[11] *See Initiation Notice,* 81 FR at 9438–39.

[12] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, "Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries," dated April 5, 2005 (Policy Bulletin 05.1), available on the Department's Web site at *http://enforcement.trade.gov/policy/bull05-1.pdf.*

Exporter	Producer	Weighted average margin (%)
Briway Tire Co., Ltd	Shandong Province Sanli Tire Manufactured Co., Ltd	20.87
Briway Tire Co., Ltd	Shandong Vheal Group Co., Ltd	20.87
Briway Tire Co., Ltd	Shandong Wanda Boto Tyre Co., Ltd	20.87
Briway Tire Co., Ltd	Shandong Yinbao Tyre Group Co., Ltd	20.87
Briway Tire Co., Ltd	Shandong Yuelong Group	20.87
Briway Tire Co., Ltd	Sichuan Tyre & Rubber Co., Ltd	20.87
Briway Tire Co., Ltd	Weifang Shunfuchang Rubber and Plastic Products Co., Ltd	20.87
Briway Tire Co., Ltd	Sichuan Kalevei Technology Co., Ltd	20.87
Chonche Auto Double Happiness Tyre Corp. Ltd	Chonche Auto Double Happiness Tyre Corp. Ltd	20.87
Chongqing Hankook Tire Co., Ltd	Chongqing Hankook Tire Co., Ltd	20.87
Cooper Tire (China) Investment Co., Ltd	Qingdao Ge Rui Da Rubber Co., Ltd	20.87
Daking Industrial Co., Limited	Shandong Huasheng Rubber Co., Ltd	20.87
Fleming Limited	Qingdao Doublestar Tire Industrial Co., Ltd	20.87
Fleming Limited	Qingdao Yellow Sea Rubber Co., Ltd	20.87
Fleming Limited	Shandong Wanshine Tire Co., Ltd	20.87
Fleming Limited	Shandong Yinbao Tyre Group Co., Ltd	20.87
Giti Tire (Anhui) Company Ltd	Giti Tire (Anhui) Company Ltd	20.87
Giti Tire (Anhui) Company Ltd	Giti Tire (Fujian) Company Ltd	20.87
Giti Tire (Anhui) Company Ltd	Giti Tire (Yinchuan) Company Ltd	20.87
Giti Tire (Fujian) Company Ltd	Giti Tire (Anhui) Company Ltd	20.87
Giti Tire (Fujian) Company Ltd	Giti Tire (Fujian) Company Ltd	20.87
Giti Tire (Fujian) Company Ltd	Giti Tire (Yinchuan) Company Ltd	20.87
Giti Tire (Yinchuan) Company Ltd	Giti Tire (Anhui) Company Ltd	20.87
Giti Tire (Yinchuan) Company Ltd	Giti Tire (Fujian) Company Ltd	20.87
Giti Tire (Yinchuan) Company Ltd	Giti Tire (Yinchuan) Company Ltd	20.87
Giti Tire Global Trading Pte. Ltd	Giti Tire (Anhui) Company Ltd	20.87
Giti Tire Global Trading Pte. Ltd	Giti Tire (Fujian) Company Ltd	20.87
Giti Tire Global Trading Pte. Ltd	Giti Tire (Yinchuan) Company Ltd	20.87
Goodyear Dalian Tire Co., Ltd	Goodyear Dalian Tire Co., Ltd	20.87
Hongkong Tiancheng Investment & Trading Co., Limited	Shandong Linglong Tyre Co., Ltd	20.87
Hongtyre Group Co.	Prinx Chengshan (Shandong) Tire Co., Ltd	20.87
Hongtyre Group Co.	Shandong Bayi Tyre Manufacture Co., Ltd	20.87
Jiangsu General Science Technology Co., Ltd	Jiangsu General Science Technology Co., Ltd	20.87
Jiangsu Hankook Tire Co., Ltd	Jiangsu Hankook Tire Co., Ltd	20.87
Koryo International Industrial Limited	Chaoyang Long March Tyre Co., Ltd	20.87
Koryo International Industrial Limited	Shandong Anchi Tyres Co., Ltd	20.87
Koryo International Industrial Limited	Shandong Hugerubber Co., Ltd	20.87
Koryo International Industrial Limited	Shandong Sangong Rubber Co., Ltd	20.87
Koryo International Industrial Limited	Shandong Wanshine Tire Co., Ltd	20.87
Koryo International Industrial Limited	Sichuan Tyre & Rubber Co., Ltd	20.87
Kumho Tire Co., Inc.	Nanjing Kumho Tire Co., Ltd	20.87
Longkou Xinglong Tyre Co., Ltd	Longkou Xinglong Tyre Co., Ltd	20.87
Maxon Int'l Co., Limited	Shandong Anchi Tyres Co., Ltd	20.87
Maxon Int'l Co., Limited	Triangle Tyre Co., Ltd	20.87
Megalith Industrial Group Co., Ltd	Ningxia Shenzhou Tire Co., Ltd	20.87
Megalith Industrial Group Co., Ltd	Shaanxi Yanchang Petroleum Group Rubber Co., Ltd	20.87
Megalith Industrial Group Co., Ltd	Shandong Hawk International Rubber Industry Co., Ltd	20.87
Megalith Industrial Group Co., Ltd	Shandong Huasheng Rubber Co., Ltd	20.87
Megalith Industrial Group Co., Ltd	Shandong Kaixuan Rubber Co., Ltd	20.87
Megalith Industrial Group Co., Ltd	Sichuan Kalevei Technology Co., Ltd	20.87
Megalith Industrial Group Co., Ltd	Xingyuan Tire Group Co., Ltd	20.87
Michelin Asia-Pacific Export (HK) Limited	Michelin Shenyang Tire Co., Ltd	20.87
Newland Tyre Int'l Limited	Shandong Hawk International Rubber Industry Co., Ltd	20.87
Noble Manufacture Co., Ltd	Qingdao Hongchi Tyre Co., Ltd	20.87
Philixx Tyres and Accessories Limited	Shandong Huasheng Rubber Co., Ltd	20.87
Philixx Tyres and Accessories Limited	Xingyuan Tire Group Co., Ltd	20.87
Philixx Tyres and Accessories Limited	Shandong Vheal Group Co., Ltd	20.87
Q&J Industrial Group Co., Limited	Chaoyang Langma Co., Ltd	20.87
Q&J Industrial Group Co., Limited	Qiangdao Huanghai Rubber Co., Ltd	20.87
Q&J Industrial Group Co., Limited	Shandong Hongsheng Rubber Co., Ltd	20.87
Q&J Industrial Group Co., Limited	Shandong Huasheng Rubber Co., Ltd	20.87
Q&J Industrial Group Co., Limited	Shandong Xingyuan Group	20.87
Q&J Industrial Group Co., Limited	Sichuan Kailiwei Technology Co., Ltd	20.87
Qingdao Au-Shine Group Co., Ltd	Shandong Gulun Rubber Co., Ltd	20.87
Qingdao Champion International Trading Co., Ltd	Shandong Cocrea Tyre Co., Ltd	20.87
Qingdao Champion International Trading Co., Ltd	Shandong Huasheng Rubber Co., Ltd	20.87
Qingdao Champion International Trading Co., Ltd	Zhucheng Sinoroad Rubber Co., Ltd	20.87
Qingdao Fudong Tyre Co., Ltd	Qingdao Fudong Tyre Co., Ltd	20.87
Qingdao Fudong Tyre Co., Ltd	Qingdao Xiyingmen Double Camel Tyre Co., Ltd	20.87
Qingdao Fullrun Tyre Corp. Ltd	Aeolus Tyre Co., Ltd	20.87
Qingdao Fullrun Tyre Corp. Ltd	Chaoyang Long March Tyre Co., Ltd	20.87

Exporter	Producer	Weighted average margin (%)
Qingdao Fullrun Tyre Corp. Ltd	Chonche Auto Double Happiness Tyre Corp. Ltd	20.87
Qingdao Fullrun Tyre Corp. Ltd	Double Coin Holdings Ltd	20.87
Qingdao Fullrun Tyre Corp. Ltd	Hangzhou Zhongce Rubber Co., Ltd	20.87
Qingdao Fullrun Tyre Corp. Ltd	Qingdao Yellow Sea Rubber Co., Ltd	20.87
Qingdao Fullrun Tyre Corp. Ltd	Qingdao Doublestar Tire Industrial Co., Ltd	20.87
Qingdao Fullrun Tyre Corp. Ltd	Shandong Xingyuan International Trading Co., Ltd	20.87
Qingdao Ge Rui Da Rubber Co., Ltd	Qingdao Ge Rui Da Rubber Co., Ltd	20.87
Qingdao Honghua Tyre Factory	Qingdao Honghua Tyre Factory	20.87
Qingdao Jinhaoyang International Co., Ltd	Double Coin Holdings Ltd	20.87
Qingdao Jinhaoyang International Co., Ltd	Qingdao Fudong Tyre Co., Ltd	20.87
Qingdao Jinhaoyang International Co., Ltd	Shaanxi Yanchang Petroleum Group Rubber Co., Ltd	20.87
Qingdao Jinhaoyang International Co., Ltd	Zhucheng Guoxin Rubber Co., Ltd	20.87
Qingdao Keter International Co., Ltd	Beijing Landy Tire & Tech Co., Ltd	20.87
Qingdao Keter International Co., Ltd	Chaoyang Long March Tyre Co., Ltd	20.87
Qingdao Keter International Co., Ltd	Chonche Auto Double Happiness Tyre Corp. Ltd	20.87
Qingdao Keter International Co., Ltd	Deruibo Tire Co., Ltd	20.87
Qingdao Keter International Co., Ltd	Qingdao Doublestar Tire Industrial Co., Ltd	20.87
Qingdao Keter International Co., Ltd	Shandong Huasheng Rubber Co., Ltd	20.87
Qingdao Keter International Co., Ltd	Shandong Huge Rubber Co., Ltd	20.87
Qingdao Keter International Co., Ltd	Shandong Kaixuan Rubber Co., Ltd	20.87
Qingdao Lakesea Tyre Co., Ltd	Chaoyang Long March Tyre Co., Ltd	20.87
Qingdao Lakesea Tyre Co., Ltd	Chonche Auto Double Happiness Tyre Corp. Ltd	20.87
Qingdao Lakesea Tyre Co., Ltd	Doublestar Dongfeng Tyre Co., Ltd	20.87
Qingdao Lakesea Tyre Co., Ltd	Qingdao Doublestar Tire Industrial Co., Ltd	20.87
Qingdao Lakesea Tyre Co., Ltd	Qingdao Yellow Sea Rubber Co., Ltd	20.87
Qingdao Lakesea Tyre Co., Ltd	Shandong Kaixuan Rubber Co., Ltd	20.87
Qingdao Lakesea Tyre Co., Ltd	Shandong Xingyuan International Trading Co., Ltd	20.87
Qingdao Lakesea Tyre Co., Ltd	Shandong Yinbao Tyre Group Co., Ltd	20.87
Qingdao Lakesea Tyre Co., Ltd	Sichuan Kalevei Technology Co., Ltd	20.87
Qingdao Nama Industrial Co., Ltd	Chaoyang Long March Tyre Co., Ltd	20.87
Qingdao Nama Industrial Co., Ltd	China National Tyre And Rubber Guilin Co., Ltd	20.87
Qingdao Nama Industrial Co., Ltd	Ningxia Shenzhou Tire Co., Ltd	20.87
Qingdao Nama Industrial Co., Ltd	Qingdao Doublestar Tire Industrial Co., Ltd	20.87
Qingdao Nama Industrial Co., Ltd	Shandong Hawk International Rubber Industry Co., Ltd	20.87
Qingdao Nama Industrial Co., Ltd	Shandong Hengfeng Rubber & Plastic Co., Ltd	20.87
Qingdao Nama Industrial Co., Ltd	Shandong Hengyu Science & Technology Co., Ltd	20.87
Qingdao Nama Industrial Co., Ltd	Shandong Huasheng Rubber Co., Ltd	20.87
Qingdao Nama Industrial Co., Ltd	Shandong Kaixuan Rubber Co., Ltd	20.87
Qingdao Nama Industrial Co., Ltd	Shandong Wanda Boto Tyre Co., Ltd	20.87
Qingdao Nama Industrial Co., Ltd	Shandong Wanshine Tyre Co., Ltd	20.87
Qingdao Odyking Tyre Co., Ltd	Weifang Shunfuchang Rubber And Plastic Products Co., Ltd	20.87
Qingdao Qianzhen Tyre Co., Ltd	Qingdao Qianzhen Tyre Co., Ltd	20.87
Qingdao Qizhou Rubber Co., Ltd	Qingdao Qizhou Rubber Co., Ltd	20.87
Qingdao Rhino International Co., Ltd	Dongying JinZheng Tyre Co., Ltd	20.87
Qingdao Rhino International Co., Ltd	Qingdao Aonuo Group	20.87
Qingdao Rhino International Co., Ltd	Shandong Jinwangda Tire Co., Ltd	20.87
Qingdao Rhino International Co., Ltd	Weihai Ping'an Tyre Co., Ltd	20.87
Qingdao Taihao Tyre Co., Ltd	Qingdao Taihao Tyre Co., Ltd	20.87
Qingdao Tanco Tire Industrial & Commercial Co., Ltd	Hebei Tianrui Rubber Co., Ltd	20.87
Qingdao Tanco Tire Industrial & Commercial Co., Ltd	Shandong Hawk International Rubber Co., Ltd	20.87
Qingdao Tanco Tire Industrial & Commercial Co., Ltd	Xingyuan Tires Group	20.87
Qingdao Yellow Sea Rubber Co., Ltd	Qingdao Yellow Sea Rubber Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Aeolus Tyre Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Bayi Rubber Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Chonche Auto Double Happiness Tyre Corp. Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Double Coin Holdings Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Guizhou Tyre Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Hangzhou Zhongce Rubber Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Qingdao Doublestar Tire Industrial Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Shandong Haohua Tire Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Shandong Hawk International Rubber Industry Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Shandong Hengfeng Rubber and Plastic Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Shandong Hengyu Science & Technology Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Shandong Huasheng Rubber Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Shandong Kaixuan Rubber Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Shandong Wosen Rubber Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Shandong Yongtai Group Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Shengtai Group Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	South China Tire & Rubber Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Weifang Goldshield Tire Co., Ltd	20.87
Qingdao Yongdao International Trade Co., Ltd	Weifang Shunfuchang Rubber & Plastic Products Co., Ltd	20.87

Exporter	Producer	Weighted average margin (%)
Qingdao Yongdao International Trade Co., Ltd	Xingyuan Tire Group Co., Ltd	20.87
Rodeo Tire Ltd	Shandong Province Sanli Tire Manufactured Co., Ltd	20.87
Rodeo Tire Ltd	Sichuan Tyre & Rubber Co., Ltd	20.87
Rover Tire Co., Ltd	Aeolus Tyre Co., Ltd	20.87
Rover Tire Co., Ltd	Dongying Fangxing Rubber Co., Ltd	20.87
Rover Tire Co., Ltd	Double Coin Holdings Ltd	20.87
Rover Tire Co., Ltd	Qingdao Doublestar Tire Industrial Co., Ltd	20.87
Rover Tire Co., Ltd	Shandong Hengyu Science & Technology Co., Ltd	20.87
Rover Tire Co., Ltd	Shandong Huasheng Rubber Co., Ltd	20.87
Rover Tire Co., Ltd	Shandong Kaixuan Rubber Co., Ltd	20.87
Rover Tire Co., Ltd	Shandong Longyue Rubber Co., Ltd	20.87
Rover Tire Co., Ltd	Shandong Yongsheng Rubber Group Co., Ltd	20.87
Rover Tire Co., Ltd	Wanli Group Trade Limited	20.87
Rover Tire Co., Ltd	Zhongce Rubber Group Company Limited	20.87
Sailun Jinyu Group Co., Ltd	Sailun Jinyu Group Co., Ltd	20.87
Sailun Jinyu Group Co., Ltd	Shenyang Peace Radial Tyre Manufacturing Co., Ltd	20.87
Shandong Anchi Tyres Co., Ltd	Shandong Anchi Tyres Co., Ltd	20.87
Shandong Haohua Tire Co., Ltd	Shandong Haohua Tire Co., Ltd	20.87
Shandong Haoyu Rubber Co., Ltd	Shandong Haoyu Rubber Co., Ltd	20.87
Shandong Hawk International Rubber Industry Co., Ltd	Shandong Hawk International Rubber Industry Co., Ltd	20.87
Shandong Hengfeng Rubber & Plastic Co., Ltd	Shandong Hengfeng Rubber & Plastic Co., Ltd	20.87
Shandong Hengyu Science & Technology Co., Ltd	Shandong Hengyu Science & Technology Co., Ltd	20.87
Shandong Hengyu Science & Technology Co., Ltd	Shandong Hengyu Rubber Co., Ltd	20.87
Shandong Homerun Tires Co., Ltd	Good Friend Tyre Co., Ltd	20.87
Shandong Homerun Tires Co., Ltd	Shandong Kaixuan Rubber Co., Ltd	20.87
Shandong Homerun Tires Co., Ltd	Shandong Wosen Rubber Co., Ltd	20.87
Shandong Homerun Tires Co., Ltd	Shandong Yongsheng Rubber Group Co., Ltd	20.87
Shandong Homerun Tires Co., Ltd	Weifang Shunfuchang Rubber and Plastic Products Co., Ltd	20.87
Shandong Huasheng Rubber Co., Ltd	Shandong Huasheng Rubber Co., Ltd	20.87
Shandong Hugerubber Co., Ltd	Shandong Hugerubber Co., Ltd	20.87
Shandong Huitong Tyre Co., Ltd	Shandong Huitong Tyre Co., Ltd	20.87
Shandong Kaixuan Rubber Co., Ltd	Shandong Kaixuan Rubber Co., Ltd	20.87
Shandong Linglong Tyre Co., Ltd	Shandong Linglong Tyre Co., Ltd	20.87
Shandong O'Green Tyres Co., Ltd	Shandong O'Green Tyres Co., Ltd	20.87
Shandong Province Sanli Tire Manufactured Co., Ltd	Shandong Province Sanli Tire Manufactured Co., Ltd	20.87
Shandong Sangong Rubber Co., Ltd	Shandong Sangong Rubber Co., Ltd	20.87
Shandong Transtone Tyre Co., Ltd	Shandong Haohua Tire Co., Ltd	20.87
Shandong Transtone Tyre Co., Ltd	Shandong Hongyu Rubber Co., Ltd	20.87
Shandong Transtone Tyre Co., Ltd	Shandong Kaixuan Rubber Co., Ltd	20.87
Shandong Transtone Tyre Co., Ltd	Weifang Yuelong Rubber Co., Ltd	20.87
Shandong Vheal Group Co., Ltd	Shandong Vheal Group Co., Ltd	20.87
Shandong Wanda Boto Tyre Co., Ltd	Shandong Wanda Boto Tyre Co., Ltd	20.87
Shandong Wanshine Tire Co., Ltd	Shandong Wanshine Tire Co., Ltd	20.87
Shandong Xingyuan Tire Group Co., Ltd	Shandong Xingyuan Tire Group Co., Ltd	20.87
Shandong Yinbao Tyre Group Co., Ltd	Shandong Yinbao Tyre Group Co., Ltd	20.87
Shandong Yongfeng Tyres Co., Ltd	Shandong Yongfeng Tyres Co., Ltd	20.87
Shandong Yongsheng Rubber Group Co., Ltd	Shandong Yongsheng Rubber Group Co., Ltd	20.87
Shandong Yongtai Group Co., Ltd	Shandong Yongtai Group Co., Ltd	20.87
Shanghai Durotyre International Trading Co., Ltd	Chaoyang Long March Tyre Co., Ltd	20.87
Shanghai Durotyre International Trading Co., Ltd	Double Happiness Tyre Industrial Co., Ltd	20.87
Shengtai Group Co., Ltd	Shengtai Group Co., Ltd	20.87
Shengtai Group Co., Ltd	Shandong Zhushenghua Rubber Co., Ltd	20.87
Shenzhen Zhongjin Import & Export Co., Ltd	Hefei Wanli Tire Co., Ltd	20.87
Shenzhen Zhongjin Import & Export Co., Ltd	South China Tire & Rubber Co.	20.87
Shenzhen Zhongjin Import & Export Co., Ltd	Weifang Shunfuchang Rubber And Plastics Products Co., Ltd	20.87
Shifeng Juxing Tire Co., Ltd	Shifeng Juxing Tire Co., Ltd	20.87
Shuma Tyre International (Qingdao) Co., Ltd	Shandong Wanshine Tire Co., Ltd	20.87
Sichuan Kalevei Technology Co., Ltd	Sichuan Kalevei Technology Co., Ltd	20.87
Sinotyre International Group Co., Ltd	Dongying City Fangxing Rubber Co., Ltd	20.87
Sinotyre International Group Co., Ltd	Shandong Hawk International Rubber Industry Co., Ltd	20.87
Sportrak Tire Group Limited	Bayi Rubber Co., Ltd	20.87
Sportrak Tire Group Limited	Shaanxi Yanchang Petroleum Group Rubber Co., Ltd	20.87
Sportrak Tire Group Limited	Shandong Hawk International Rubber Industry Co., Ltd	20.87
Tianjin Leviathan International Trade Co., Ltd	NDI Tire (Qingdao) Co., Ltd	20.87
Tianjin Leviathan International Trade Co., Ltd	Qingdao Nama Industrial Co., Ltd	20.87
Tianjin Leviathan International Trade Co., Ltd	Shandong Haohua Tire Co., Ltd	20.87
Tianjin Leviathan International Trade Co., Ltd	Shandong Hawk International Rubber Industry Co., Ltd	20.87
Tianjin Leviathan International Trade Co., Ltd	Xingyuan Tire Group Co., Ltd	20.87
Top Tyre Industry Co., Limited	Shandong Hawk International Rubber Industry Co., Ltd	20.87
Toyo Tire (Zhucheng) Co., Ltd	Toyo Tire (Zhucheng) Co., Ltd	20.87
Triangle Tyre Co., Ltd	Triangle Tyre Co., Ltd	20.87

Exporter	Producer	Weighted average margin (%)
Tyrechamp Group Co., Limited	South China Tire & Rubber Co., Ltd	20.87
Tyrechamp Group Co., Limited	Zhongce Rubber Group Company Limited	20.87
Wanli Group Trade Limited	South China Tire & Rubber Co., Ltd,	20.87
Weifang Shunfuchang Rubber And Plastic Products Co., Ltd	Weifang Shunfuchang Rubber And Plastic Products Co., Ltd	20.87
Weihai Ping'an Tyre Co., Ltd	Weihai Ping'an Tyre Co., Ltd	20.87
Weihai Zhongwei Rubber Co., Ltd	Weihai Zhongwei Rubber Co., Ltd	20.87
Wendeng Sanfeng Tyre Co., Ltd	Wendeng Sanfeng Tyre Co., Ltd	20.87
Xuzhou Xugong Tyres Co., Ltd	Xuzhou Xugong Tyres Co., Ltd	20.87
Xuzhou Xugong Tyres Co., Ltd	Armour Rubber Company Ltd	20.87
Yokohama Rubber Co., Ltd	Suzhou Yokohama Tire Co., Ltd	20.87
Yongsheng Group Co., Ltd	Shandong Yongsheng Rubber Group Co., Ltd	20.87
Zhongce Rubber Group Co., Ltd	Zhongce Rubber Group Co., Ltd	20.87
Zhucheng Guoxin Rubber Co., Ltd	Zhucheng Guoxin Rubber Co., Ltd	20.87
PRC-Wide Entity		22.57

As detailed in the Preliminary Decision Memorandum, Double Coin Holdings Ltd., a mandatory respondent in this investigation, did not demonstrate that it was entitled to a separate rate. Accordingly, we consider this company to be part of the PRC-wide entity.

Suspension of Liquidation

In accordance with sections 733(e)(2)(A) of the Act, we will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of truck and bus tires from the PRC, as described in Appendix I, that are entered, or withdrawn from warehouse, for consumption on or after 90 days prior to the date of publication of this notice in the **Federal Register**, and to require a cash deposit for such entries.

Pursuant to 19 CFR 351.205(d), the Department will instruct CBP to require a cash deposit [13] equal to the weighted-average amount by which NV exceeds U.S. price as follows: (1) The cash deposit rate for the exporter/producer combinations listed in the table above will be the rate identified in the table; (2) for all combinations of PRC exporters/producers of merchandise under consideration that have not received their own separate rate above, the cash-deposit rate will be the cash deposit rate established for the PRC-wide entity; and (3) for all non-PRC exporters of merchandise under consideration which have not received their own separate rate above, the cash-deposit rate will be the cash deposit rate applicable to the PRC exporter/producer combination that supplied that non-PRC exporter. These suspensions of liquidation instructions will remain in effect until further notice.

With respect to PCT, the non-selected respondents eligible for a separate rate, and the PRC-wide entity, we find that export subsidies constitute 0.41 percent [14] of the preliminarily calculated countervailing duty rate in the concurrent countervailing duty investigation. Thus, we will offset the rate of 20.87 percent for PCT and the non-selected respondents eligible for a separate rate and the rate of 22.57 percent for the PRC-wide entity by countervailing duty rate attributable to export subsidies, *i.e.,* 0.41 percent, to calculate the cash deposit rate for this investigation. Accordingly, the cash deposit rates will be 20.46 percent for PCT and the non-selected respondents eligible for a separate rate and 22.16 percent for the PRC-wide entity.

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days after public announcement of the preliminary determination in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i) of the Act, we intend to verify information relied upon in making our final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the final verification report is issued in this proceeding and rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[15] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5:00 p.m. Eastern Time, within 30 days after the date of publication of this notice.[16] Hearing requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues parties intend to present at the hearing. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW.,

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[13] *See Modification of Regulations Regarding the Practice of Accepting Bonds During the Provisional Measures Period in Antidumping and Countervailing Duty Investigations,* 76 FR 61042 (October 3, 2011).

[14] The Department preliminarily determined that Export Seller's Credit from the Export-Import Bank of China was export specific and, from this program, Double Coin and Guizhou Tyre Co., Ltd., respectively received countervailable subsidies of 0.40 percent ad valorem and 0.41 percent ad valorem. *See Truck and Bus Tires From the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination, Preliminary Affirmative Critical Circumstances Determination, in Part, and Alignment of Final Determination With Final Antidumping Determination,* 81 FR 43577 (July 5, 2016), and accompanying Preliminary Decision Memorandum at 29. We simple-averaged these two nearly identical export subsidy rates and calculated 0.41 percent (0.405 percent rounded up) for purposes of adjusting the cash deposit rate in this investigation. *See* Preliminary Decision Memorandum at 30–31 for more details.

[15] *See* 19 CFR 351.309. *See also* 19 CFR 351.303 (for general filing requirements).

[16] *See* 19 CFR 351.310(c).

Washington, DC 20230, at a time and location to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by petitioners. Requests by respondents for postponement of a final antidumping determination must be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.[17]

Pursuant to 19 CFR 351.210(e), we received requests from certain respondents that the Department postpone the final determination and that provisional measures be extended to a period not to exceed six months.[18]

In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because (1) our preliminary determination is affirmative; (2) the requesting exporters account for a significant proportion of exports of the subject merchandise;[19] and (3) no compelling reasons for denial exist, we are postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, we will make our final determination no later than 135 days after the date of publication of this preliminary determination, pursuant to section 735(a)(2)(A) of the Act.[20]

U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, we will notify the U.S. International Trade Commission (ITC) of our affirmative preliminary determination of sales at LTFV. If our final determination in this investigation is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.[21]

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: August 26, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of the investigation covers truck and bus tires. Truck and bus tires are new pneumatic tires, of rubber, with a truck or bus size designation. Truck and bus tires covered by this investigation may be tube-type, tubeless, radial, or non-radial.

Subject tires have, at the time of importation, the symbol "DOT" on the sidewall, certifying that the tire conforms to applicable motor vehicle safety standards. Subject tires may also have one of the following suffixes in their tire size designation, which also appear on the sidewall of the tire:

TR—Identifies tires for service on trucks or buses to differentiate them from similarly sized passenger car and light truck tires;

MH—Identifies tires for mobile homes; and

HC—Identifies a 17.5 inch rim diameter code for use on low platform trailers.

All tires with a "TR," "MH," or "HC" suffix in their size designations are covered by this investigation regardless of their intended use.

In addition, all tires that lack one of the above suffix markings are included in the scope, regardless of their intended use, as long as the tire is of a size that is among the numerical size designations listed in the "Truck-Bus" section of the *Tire and Rim Association Year Book,* as updated annually, unless the tire falls within one of the specific exclusions set out below.

Truck and bus tires, whether or not mounted on wheels or rims, are included in the scope. However, if a subject tire is imported mounted on a wheel or rim, only the tire is covered by the scope. Subject merchandise includes truck and bus tires produced in the subject country whether mounted on wheels or rims in the subject country or in a third country. Truck and bus tires are covered whether or not they are accompanied by other parts, *e.g.,* a wheel, rim, axle parts, bolts, nuts, etc. Truck and bus tires that enter attached to a vehicle are not covered by the scope.

Specifically excluded from the scope of this investigation are the following types of tires: (1) Pneumatic tires, of rubber, that are not new, including recycled and retreaded tires; and (2) non-pneumatic tires, such as solid rubber tires.

The subject merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4011.20.1015 and 4011.20.5020. Tires meeting the scope description may also enter under the following HTSUS subheadings: 4011.99.4520, 4011.99.4590, 4011.99.8520, 4011.99.8590, 8708.70.4530, 8708.70.6030, and 8708.70.6060. On August 26, 2016, the Department included HTSUS subheadings 4011.69.0020, 4011.69.0090, and 8716.90.5059 to the case reference files, pursuant to requests by U.S. Customs and Border Protection and the petitioner.[22]

While HTSUS subheadings are provided for convenience and for customs purposes, the written description of the subject merchandise is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Selection of Respondents
IV. Period of Investigation
V. Scope Comments
VI. Scope of the Investigation
VII. Product Characteristics
VIII. Critical Circumstances
IX. Discussion of the Methodology
  A. Non-Market Economy Country
  B. Surrogate Country
  C. Surrogate Value Comments
  D. Separate Rates
  E. Dumping Margin for the Separate Rate Companies
  F. Combination Rates
  G. The PRC-Wide Entity
  H. Application of Facts Available and Adverse Inferences
  I. Date of Sale
  J. Fair Value Comparisons
  K. Export Price
  L. Normal Value
  M. Factor Valuation Methodology
  N. Currency Conversion
X. Adjustment Under Section 777A(F) of the Act
XI. Adjustment to Cash Deposit Rate for Export Subsidies
XII. Verification
XIII. U.S. ITC Notification
XIV. Conclusion

[FR Doc. 2016–21346 Filed 9–2–16; 8:45 am]

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[17] *See* 19 CFR 351.210(e)(2).

[18] *See* Letter from PCT, "Truck and Bus Tires from China: Extension Request for Final Determination by Prinx Chengshan (Shandong) Tire Co., Ltd.," dated August 25, 2016, and Letter from Double Coin Holdings Ltd., "Double Coin's Request to Extend the Final Determination," dated August 26, 2016.

[19] *See* Memorandum to Deputy Assistant Secretary Christian Marsh entitled, "Antidumping Duty Investigation of Truck and Bus Tires from the People's Republic of China: Respondent Selection," dated April 18, 2016.

[20] *See also* 19 CFR 351.210(e).

[21] *See* section 735(b)(2) of the Act.

[22] *See* Memorandum to the File entitled, "Requests from Customs and Border Protection and the Petitioner to Update the ACE Case Reference File," dated August 26, 2016.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Analysis and Review of Ocean Exploration Video Products

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before September 15, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Nick Pawlenko, LTJG/NOAA. NOAA Office of Ocean Exploration and Research, 215 South Ferry Road, Narragansett, RI 02882 (401) 874–6478.

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for a new information collection.

Telepresence uses satellite communication from ship to shore to bring the unknown ocean to the screens of scientists and the general public in their homes, schools or offices. With technology constantly evolving it is important to address the needs of the shore based scientists and public to maintain a high level of participation. We will use voluntary surveys to identify the needs of users of data, best approaches to leverage expertise of shore based participants and to create a "Citizen Science" web portal for meaningful public engagement focused on ocean exploration.

II. Method of Collection

This will be a web-based survey.

III. Data

OMB Control Number: 0648-xxxx.

Form Number(s): None.

Type of Review: Regular (new information collection).

Affected Public: Individuals or households; business or other for-profit organizations; not-for-profit institutions; Federal government.

Estimated Number of Respondents: 1000.

Estimated Time Per Response: 5 minutes.

Estimated Total Annual Burden Hours: 83 hours.

Estimated Total Annual Cost to Public: $0 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: August 31, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–21317 Filed 9–2–16; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE858

Western Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting and hearing.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold a meeting of its Commonwealth of the Northern Mariana Islands (CNMI) Mariana Archipelago Fishery Ecosystem Plan (FEP) Advisory Panel (AP) and Guam Mariana Archipelago FEP AP to discuss and make recommendations on fishery management issues in the Western Pacific Region.

DATES: The CNMI Mariana Archipelago FEP AP will meet on Wednesday, September 21, 2016, between 6 p.m. and 9 p.m. and the Guam Mariana Archipelago FEP AP will meet on Saturday, September 24, 2016, between 1 p.m. and 5 p.m. All times listed are local island times. For specific times and agendas, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The CNMI Mariana Archipelago FEP AP will meet at the Hyatt Regency Saipan, Royal Palm Avenue, Micro Beach Road, Garapan, Saipan, CNMI 96950. The Guam Mariana Archipelago FEP AP will meet at the Hilton Guam Resort and Spa, 202 Hilton Road, Tumon Bay, Guam 96913.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: Public comment periods will be provided in the agenda. The order in which agenda items are addressed may change. The meetings will run as late as necessary to complete scheduled business.

Schedule and Agenda for the CNMI Mariana Archipelago FEP AP Meeting

Wednesday, September 21, 2016, 6 p.m.–9 p.m.

1. Welcome and Introductions
2. Outstanding Council Action Items
3. Council Issues
   A. 2017 U.S. Territory Bigeye Tuna Limits
   B. Council Coral Reef Projects
   C. Report on Military Activities and Issues
4. Update on Council Projects in the Marianas
   A. Coral Reef Projects
   B. Data Collection Projects
   C. Community-Based Projects
5. Mariana FEP Community Activities
6. Marianas FEP AP–CNMI Issues
   A. Report of the Subpanels
   i. Island Fisheries Subpanel
   ii. Pelagic Fisheries Subpanel
   iii. Ecosystems and Habitat Subpanel
   iv. Indigenous Fishing Rights Subpanel
   B. Other Issues
7. Public Comment
8. Discussion and Recommendations
9. Other Business

Schedule and Agenda for the Guam Mariana Archipelago FEP AP Meeting

Saturday, September 24, 2016, 1 p.m.–5 p.m.

1. Hafa Adai—Welcome and Introductions
2. Outstanding Council Action Items
3. Council Issues
   A. 2017 U.S. Territory Bigeye Tuna Limits
   B. Council Coral Reef Projects
   C. Report on Military Activities and Issues
4. Update on Council Projects in the Marianas
   A. Coral Reef Projects
   B. Data Collection Projects
   C. Community-Based Projects
5. Mariana FEP Community Activities
6. Marianas FEP AP-Guam Issues
   A. Report of the Subpanels
   i. Island Fisheries Subpanel
   ii. Pelagic Fisheries Subpanel
   iii. Ecosystems and Habitat Subpanel
   iv. Indigenous Fishing Rights Subpanel
   B. Other Issues
7. Public Comment
8. Discussion and Recommendations
9. "At the End of the Day"—Other Business

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 31, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–21314 Filed 9–2–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Proposed Information Collection; Comment Request; Limited Access Death Master File Accredited Conformity Assessment Body Application for Firewalled Status

AGENCY: National Technical Information Service, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. The purpose of this notice is to allow for 60 days of public comment.

DATES: Written comments must be submitted on or before November 7, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to John W. Hounsell, Business and Industry Specialist, Office of Product and Program Management, National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312, email: *jhounsell@ntis.gov* or telephone: 703–605–6184

SUPPLEMENTARY INFORMATION:

I. Abstract

This notice informs the public that the National Technical Information Service (NTIS) is requesting approval of a new information collection described in Section II for use in connection with the final rule entitled "Certification Program for Access to the Death Master File." The final rule was published on June 1, 2016, and will become effective on November 28, 2016. The new information collection described in Section II, if approved, will become effective on the effective date of the final rule.

II. Method of Collection

Title of Information Collection: "Limited Access Death Master File Accredited Conformity Assessment Body Application for Firewalled Status" (Firewalled Status Application Form).

Description of the need for the information and the proposed use: NTIS issued a final rule establishing a program through which persons may become eligible to obtain access to Death Master File (DMF) information about an individual within three years of that individual's death. The final rule was promulgated under Section 203 of the Bipartisan Budget Act of 2013, Public Law 113–67 (Act). The Act prohibits the Secretary of Commerce (Secretary) from disclosing DMF information during the three-year period following an individual's death (Limited Access DMF), unless the person requesting the information has been certified to access the Limited Access DMF pursuant to certain criteria in a program that the Secretary establishes. The Secretary delegated the authority to carry out Section 203 to the Director of NTIS.

The final rule requires that, in order to become certified, a Person must submit a written attestation from an "Accredited Conformity Assessment Body" (ACAB), as defined in the final rule, that such Person has information security systems, facilities and procedures in place to protect the security of the Limited Access DMF, as required under Section 1110.102(a)(2) of the final rule. A Certified Person also must provide a new written attestation periodically for renewal of its certification as specified in the final rule. The ACAB must be independent of the Person or Certified Person seeking certification, unless it is a conformity assessment body which qualifies for "firewalled status" pursuant to Section 1110.502 of the final rule.

The Firewalled Status Application Form collects information that NTIS will use to evaluate whether the respondent qualifies for "firewalled status" under the rule, and, therefore, can provide a written attestation in lieu of an independent ACAB's attestation. This information includes specific requirements of Section 1110.502(b) of the final rule, which the respondent ACAB must certify are satisfied, and the provision of specific information by the respondent ACAB, such as the identity of the Person or Certified Person that would be the subject of the attestation and the basis upon which the certifications were made.

III. Data

OMB Control Number: This is a new collection.

Form Number(s): NTIS FM101.

Type of Review: Regular.

Affected Public: Accredited Conformity Assessment Bodies seeking firewalled status under 15 CFR 1110.502 because they are "owned, managed or controlled" by the Person or Certified Person for whom they are providing assessment(s) and or audit(s) under the final rule for the "Certification Program for Access to the Death Master File."

Estimated Number of Respondents: NTIS expects to receive approximately 560 applications and renewals for certification every year, of which it expects that approximately 20% of the required assessments will be provided by Accredited Conformity Assessment Bodies that will seek firewalled status in a given year. Accordingly, NTIS estimates that it will receive approximately 112 Firewalled Status Application Forms per year.

Estimated Time per Response: 60 minutes.

Estimated Total Annual Burden Hours: 112 (112 × 1 hour = 112 hours).

Estimated Total Annual Cost to Public: NTIS expects to receive approximately 112 applications annually at a fee of $200 per application, for a total cost to the public of $22,400. The total annual cost reflects the cost to the Federal Government, which consists of the expenses associated with NTIS personnel reviewing and processing the Firewalled Status Application Forms. In addition, NTIS estimates that it will take a senior auditor within the organization one hour to complete the form at a rate of $135 per hour, for a total additional cost to the public of $15,120 (112 burden hours × $135/hour = $15,120). NTIS estimates the total annual cost to the public to be $22,400 in fees + $15,120 in staff time = $37,520.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: August 31, 2016.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2016–21279 Filed 9–2–16; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2016–0027]

Request for Comments on the Extended Missing Parts Pilot Program

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Request for comments.

SUMMARY: The United States Patent and Trademark Office (USPTO) has a pilot program (Extended Missing Parts Pilot Program) in which an applicant, under certain conditions, can request a 12-month time period to pay the search fee, the examination fee, any excess claim fees, and the surcharge (for the late submission of the search fee and the examination fee) in a nonprovisional application. The Extended Missing Parts Pilot Program is currently set to expire on December 31, 2016. The USPTO is seeking public comment on whether the Extended Missing Parts Pilot Program offers sufficient benefits to the patent community for it to be made permanent or whether the USPTO should permit the program to expire.

DATES: *Comment Deadline Date:* Written comments must be received on or before November 7, 2016.

ADDRESSES: Comments should be sent by electronic mail message over the Internet addressed to: *extendedmissingparts2016@uspto.gov.* Comments may also be submitted by postal mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450, marked to the attention of Eugenia A. Jones.

Although comments may be submitted by postal mail, the Office prefers to receive comments by electronic mail message over the Internet in order to facilitate posting on the USPTO's Internet Web site. Electronic comments are preferred to be submitted in plain text, but also may be submitted in ADOBE® portable document format or MICROSOFT WORD® format. Comments not submitted electronically should be submitted on paper in a format that facilitates convenient digital scanning into ADOBE® portable document format.

The comments will be available for public inspection at the Office of the Commissioner for Patents, currently located in Madison East, Tenth Floor, 600 Dulany Street, Alexandria, Virginia 22314. Comments also will be available for viewing via the USPTO's Internet Web site (*http://www.uspto.gov*). Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments. It would be helpful to the USPTO if comments included information about: (1) The name and affiliation of the individual responding; and (2) an indication of whether the comments represent views of the respondent's organization or are the respondent's personal views.

FOR FURTHER INFORMATION CONTACT: Eugenia A. Jones, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, by telephone at (571) 272–7727, or Erin M. Harriman, Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, by telephone at (571) 272–7747.

SUPPLEMENTARY INFORMATION:

I. Background

On December 8, 2010, after considering written comments from the public, the USPTO implemented the Extended Missing Parts Pilot Program. *See Pilot Program for Extended Time Period To Reply to a Notice to File Missing Parts of Nonprovisional Application,* 75 FR 76401 (Dec. 8, 2010), 1362 *Off. Gaz. Pat. Office* 44 (Jan. 4, 2011). Over the course of the pilot program, the USPTO provided extensions of the Extended Missing Parts Pilot Program through notices published in the **Federal Register**. The most recent notice extended the program until December 31, 2016, to allow the USPTO time to seek public comment on whether the Extended Missing Parts Pilot Program offers sufficient benefits to the patent community for it to be made permanent. *See Extension of Extended Missing Parts Pilot Program,* 80 FR 80325 (Dec. 24, 2015), 1422 *Off. Gaz. Pat. Office* 192 (Jan. 19, 2016). Since the Extended Missing Parts Pilot Program has been in place for more than five years, it is now a good opportunity to seek public comment on whether the program offers sufficient benefits to the patent community for it to be made permanent or whether the USPTO should permit the program to expire.

Summary of the Extended Missing Parts Pilot Program: In order for an applicant to be provided a 12-month (non-extendable) time period to pay the search and examination fees and any required excess claims fees in response to a Notice to File Missing Parts of Nonprovisional Application under the Extended Missing Parts Pilot Program, the applicant must satisfy the following conditions: (1) The applicant must submit a certification and request to participate in the Extended Missing Parts Pilot Program with the nonprovisional application on filing, preferably by using Form PTO/AIA/421, titled "Certification and Request for Extended Missing Parts Pilot Program"; (2) the application must be an original (*i.e.,* not a Reissue) nonprovisional utility or plant application filed under 35 U.S.C. 111(a) within the duration of the pilot program; (3) the nonprovisional application must directly claim the benefit under 35 U.S.C. 119(e) and 37 CFR 1.78 of a prior provisional application filed within the previous 12 months, and the specific reference to the provisional application must be in an application data sheet under 37 CFR 1.76 (*see* 37 CFR 1.78(a)(3)); and (4) the applicant must not have filed a nonpublication request.

As required for all nonprovisional applications, the applicant must satisfy filing date requirements and publication requirements. If the application submitted on filing does not meet the requirements for publication, or if the application is filed without any claims, the Office of Patent Application Processing will issue an appropriate notice setting a two-month (extendable) time period within which to respond. The Extended Missing Parts Pilot Program does not change the two-month time period set forth in any such notice. In accordance with 35 U.S.C. 122(b), the USPTO will publish the application promptly after the expiration of 18 months from the earliest filing date for which benefit is sought.

If the applicant satisfies the requirements (discussed above) on filing of the nonprovisional application and the application is in condition for publication, the USPTO will send the applicant a Notice to File Missing Parts of Nonprovisional Application that sets a 12-month (non-extendable) time period to submit the search fee, the examination fee, any excess claims fees (under 37 CFR 1.16(h)-(j)), and the surcharge under 37 CFR 1.16(f) (for the late submission of the search fee and examination fee). If an applicant files a timely reply to the Notice to File Missing Parts within the 12-month time period and the nonprovisional application is completed, the nonprovisional application will be placed in the examination queue based on the actual filing date of the nonprovisional application.

For additional discussion, *see Pilot Program for Extended Time Period To Reply to a Notice to File Missing Parts of Nonprovisional Application,* 75 FR 76401 (Dec. 8, 2010), 1362 *Off. Gaz. Pat. Office* 44 (Jan. 4, 2011), and *Extension of the Extended Missing Parts Pilot Program,* 80 FR 80325 (Dec. 24, 2015), 1422 *Off. Gaz. Pat. Office* 192 (Jan. 19, 2016).

II. Request for Public Comments

The USPTO is requesting written public comments on whether the Extended Missing Parts Pilot Program should be made permanent. The USPTO seeks input from the public on the following:

1. Have you participated in the Extended Missing Parts Pilot Program? If so, please discuss what aspects of the program you think are beneficial and what aspects are not.
2. Please discuss why an applicant would be discouraged from participating in the Extended Missing Parts Pilot Program.
3. Do you think the USPTO should make the Extended Missing Parts Pilot Program permanent? Why or why not?
4. Please provide any other input that you would like the USPTO to consider in determining whether the Extended Missing Parts Pilot Program should be made permanent.

Dated: August 29, 2016.

Russell Slifer,

Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office.

[FR Doc. 2016–21306 Filed 9–2–16; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–C–2016–0032]

USPTO Cancer Moonshot Challenge

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) publishes this notice to announce the Cancer Moonshot Challenge, which was launched on August 22, 2016, to enlist the public's help to leverage the USPTO's intellectual property data, often an early indicator of meaningful research and development, and combine it with other economic and funding data. This challenge supports the goals and objectives of the National Cancer Moonshot, a Presidential initiative to speed up cancer advances, make more therapies available to more patients, and improve the ability to prevent cancer and detect it at an early stage. This notice provides the public with information on participation and application requirements for the challenge, including the judging criteria, submission requirements, and rules of eligibility.

DATES: *Challenge Deadline:* The deadline for submissions is September 12, 2016, 5:00 p.m. Eastern Standard Time (EST).

ADDRESSES: All individuals or entities who wish to participate in the challenge must register and submit their entry through *www.challenge.gov.*

FOR FURTHER INFORMATION CONTACT: For further information, please contact Thomas A. Beach, Office of the Under Secretary and Director, at 571–272–8600.

SUPPLEMENTARY INFORMATION:

I. About the Challenge

Background

Cancer is undoubtedly a disease that touches all our lives. Ending cancer as we know it requires the formation of new alliances. As President Obama noted, getting this done isn't just going to take the best and brightest across the medical, research, and data communities—but millions of Americans owning a stake of it. By harnessing the power of patent data and accelerating the process for protecting the intellectual property that leads to cancer immunotherapy breakthroughs, the USPTO is standing up and doing its part to help bring potentially life-saving treatments to patients, faster.

The Challenge

With data released through the USPTO Developer Hub, users are building rich visualizations of intellectual property data, an early indicator of meaningful innovation and research and development (R&D), and combining this data with other state or agency data, such as census and bureau of labor statistics, and/or economic and financial data. These types of visualizations demonstrate the power of telling complex stories that lead to impactful insights and ask why the data matters. Similarly, we challenge you to create and illuminate new trend lines and interactive mappings of innovation with visualizations for all types of cancer treatments and diagnostics by combining our data with other unique data. Be sure to list the sources of your data sets (*i.e.,* orange book data from the FDA), tools, and assumptions used to form your conclusion and visualizations. Imagine your data visualizations will be the foundation to empower the Federal Government—as well as the medical, research, and data communities—to make more precise funding and policy decisions based on the commercialization lifecycle of the most promising treatments, while maximizing U.S. competitiveness in cancer investments.

Using analytic tools, processes, and other interoperable data sets, we are challenging you to develop interactive visualizations and stories that can help reveal new insights to guide public policy and research to achieve the goal of doubling the rate of progress toward a cure. For example, you could address questions such as:

Trending:

- What new insights can be revealed by correlating R&D spending/funding to breakthrough technologies? How would you define or cluster the broad spectrum of cancer treatments, therapies, and/or diagnostics?
- What would trace studies of commercially successful treatments from patent to product tell us? What data insights can be gleaned from understanding the time it takes bring patents to patients?
- What are the peaks and valleys in the landscape of cancer treatment technologies?

Policy:

- If you were the Director of NIH or another agency, given what you have learned from this patent data and your research, how would you prioritize your cancer research budget? (The National Cancer Institute's FY2014 budget was $4.932 billion.)
- Based on cluster mapping of cancer treatments, therapies, and/or diagnostics, what policy would you put in place to promote certain technologies? For example, would you promote treatment to make cancer a livable disease verses curing it?
- Is there any measurable relationship between patent data, clinical trial data, and time to it takes for the technology to be in the hands of the patient? If so, how (and with what catalyst for innovation and policy changes) would you advise the VPOTUS for the Cancer Moonshot?

Resources

The USTPO has released a curated data set consisting of 269,353 patent documents (published patent applications and granted patents) spanning the 1976 to 2016 period. This data and associated documentation explaining our methodology can be found on the USPTO Developer Hub.

Prizes

First Place: $5,000.00
Second Place: $3,000.00
Third Place: $2,000.00

More Information About the Cancer Moonshot Initiative

As the President's Cancer Moonshot Initiative looks to build public-private partnerships with industry, governments, health systems, non-profits, philanthropy, research institutes, patients, and academia, those interested in advancing the Cancer Moonshot can join today by visiting *www.whitehouse.gov/CancerMoonshot.*

II. Judging Criteria

- Creativity & Innovation (20%)
  - ○ Uniqueness and innovation in approach to revealing new insights to guide public policy and research.
  - ○ Concept should be original, fill a gap, or answer a question in a manner that is not already available.
- Evidence Base & Effectiveness (20%)
  - ○ Provide meaningful insight, including potential actions and discoveries, using patent-related data to better inform funding and policy decisions or uncover insights into the cancer R&D process.
  - ○ How did you arrive at and validate your story? Did you include additional complimentary datasets to help solidify your story? What additional knowledge sources did you use?
- Value to Public (20%)
  - ○ Concept should add value to the medical, research, or data communities and policymakers, allowing them to make more informed funding and policy decisions based on the patterns and trends of innovation in cancer diagnosis and treatment.
- Usability (20%)
  - ○ The design elements should attract, engage, and influence actions from the public and policymakers.
- Functional Product (20%)
  - ○ The visualization should have demonstrable functionality as described in project description.

III. How To Enter

By September 12, 2016, 5:00 p.m. Eastern Standard Time, submit the following items through *www.challenge.gov:*

- A story (maximum 1,000 words). Written in English, tell the story of your visualization and walk users through how to use your visualization. The document must describe how your visualization provides meaningful insight, including potential actions and/or discoveries.
- Access to and testing instructions for your submission. This can be appended to your visualization description and does not count toward the 1,000 word maximum.
- Link to the submission. We will not accept any submission without a link.

IV. Rules

To be eligible to win a prize under this challenge, an individual or entity:

(1) Shall have registered to participate in the competition under the rules promulgated by the USPTO.

(2) Shall have complied with all the requirements under this section.

(3) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States; in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States.

(4) Shall not be a federal entity or federal employee acting within the scope of their employment.

(5) Shall not be a USPTO employee working on their applications or submissions during assigned duty hours.

(6) In the case of a federal grantee, shall not use federal funds to develop applications unless consistent with the purpose of their grant award.

(7) In the case of a federal contractor, shall not use federal funds from a contract to develop applications or to fund efforts in support of a challenge submission.

An individual or entity shall not be deemed ineligible because the individual or entity used federal facilities or consulted with federal employees during a competition if the facilities and employees are made equitably available to all individuals and entities participating in the competition.

Entrants must agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from their participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

Entrants must also agree to indemnify the Federal Government against third-party claims for damages arising from or related to competition activities. By entering into this competition, entrants represent that the they possess liability insurance or are otherwise financially responsible for: (1) Claims by a third party for death, bodily injury, or property damage, or loss resulting from an activity carried out in connection with participation in the competition, with the Federal Government named as an additional insured under the Entrant's insurance policy, if any; and (2) claims by the Federal Government for damage or loss to government property resulting from such an activity.

By submitting an entry to this competition you represent and warrant that your submission:

- Is your own work and not copied (if we have reason to believe that your submission is not your own work then we may not consider it);
- does not contain any third party intellectual property rights and/or content that you do not have permission to use; and
- is not obscene, defamatory, or in breach of any applicable legislation or regulations.

The USPTO reserves the right to cancel, suspend, and/or modify the challenge, or any part of it, for any reason, at the USPTO's sole discretion.

Submission Requirements

- Your submission must use at least the cancer research dataset provided by the USPTO.
- Your submission must be relevant to a U.S. audience and must be in the English language only.
- You are responsible for the cost and expense (if any) of sending your submission to us and, if your submission is selected, either attending an awards event demo at the USPTO on September 26, 2016, in person or submitting a video of your presentation to be shared at the event.
- Only one project submission is permitted per person or group. In the event of a dispute over the identity of an entrant, the submission will be deemed submitted by the authorized account holder of the email address submitted during the registration process.

Submissions that do not adhere to the requirements listed above will be automatically disqualified.

Intellectual Property

Ownership of intellectual property is determined by the following:

- Each entrant retains title and full ownership in and to their submission. Entrants expressly reserve all intellectual property rights not expressly granted under the challenge agreement.
- By participating in the challenge, each entrant hereby irrevocably grants to sponsor and administrator a limited, non-exclusive, royalty-free, worldwide license and right to reproduce, publicly perform, publicly display, and use the submission to the extent necessary to administer the challenge, and to publicly perform and publicly display the submission, including, without limitation, for advertising and promotional purposes relating to the challenge.
- All entrants are encouraged to open source their code to the extent possible as a continuing contribution to cancer research.

Dated: August 31, 2016.

Michelle K. Lee,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2016–21349 Filed 9–2–16; 8:45 am]

BILLING CODE 3510–16–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Information Collection; Submission for OMB Review, Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS) has submitted a public information collection request (ICR) entitled Senior Corps Project Progress Report (PPR)—OMB Control Number 3045–0033 for review and approval in accordance with the Paperwork Reduction Act of 1995. Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Jill Sears, at 202–606–7577 or email to *jsears@cns.gov*. Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

DATES: Comments may be submitted, identified by the title of the information collection activity, within October 6, 2016.

ADDRESSES: Comments may be submitted, identified by the title of the information collection activity, to the Office of Information and Regulatory Affairs, Attn: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service, by any of the following two methods within 30 days from the date of publication in the **Federal Register:**

(1) By fax to: 202–395–6974, Attention: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service; or

(2) By email to: *smar@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments

A 60-day Notice requesting public comment was published in the **Federal Register** on 06/10/2016 at 81 FR 37582. This comment period ended August 9, 2016. No public comments were received from this Notice.

Description: The Senior Corps PPR has two components: (1) Narratives and work plans, and (2) the Progress Report Supplement (PRS), which is an annual survey of volunteer demographics and grantee characteristics.

Type of Review: Renewal.

Agency: Corporation for National and Community Service.

Title: Senior Corps Project Progress Report.

OMB Number: 3045–0033.

Agency Number: None.

Affected Public: Sponsors of Senior Corps grants.

Total Respondents: 1,250.

Frequency: Work plans and narratives: Semi-Annual. Progress Report Supplement: Annual.

Average Time per Response: Progress Report and Supplement: Twelve hours.

Estimated Total Burden Hours: 15,000 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Authority: Pub. L. 104–13, (44 U.S.C. Chapter 35)

Dated: August 30, 2016.

Mikel Herrington,

Director, Senior Corps.

[FR Doc. 2016–21327 Filed 9–2–16; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice Is Given of the Names of Members of the Performance Review Board for the Department of the Air Force

AGENCY: United States Air Force, DOD.

ACTION: Notice.

SUMMARY: Notice is given of the names of members of the Performance Review Board for the Department of the Air Force.

DATES: Effective on November 1, 2016.

SUPPLEMENTARY INFORMATION: Pursuant to 5 U.S.C. 4314(c) (1–5), the Department of the Air Force (AF) announces the appointment of members to the AF's Senior Executive Service (SES) Performance Review Board (PRB). Appointments are made by the authorizing official. Each board member shall review and evaluate performance scores provided by the SES' immediate supervisor. Performance standards must be applied consistently across the AF. The board will make final recommendations to the authorizing official relative to the performance of the executive.

The members of the 2016 Performance Review Board for the U.S. Air Force are:

1. Board President—Gen Pawlikowski, Commander, Air Force Material Command
2. Honorable Disbrow, Under Secretary of the Air Force
3. Honorable Ballentine, Assistant Secretary of the Air Force for Installations, Environment, and Logistics
4. Lt Gen McLaughlin, Deputy Commander at United States Cyber Command
5. Lt Gen Bunch, Deputy, Office of the Assistant Secretary of the Air Force for Acquisition
6. Lt Gen Grosso, Deputy Chief of Staff for Manpower, Personnel and Services
7. Ms. Young, Executive Director, Air Force Materiel Command
8. Ms. Thomas, Deputy Chief Management Officer of the Air Force
9. Mr. McDade, Principal Deputy General Counsel of the Air Force
10. Mr. Shelton, Deputy Administrative Assistant to the Secretary of the Air Force
11. Ms. Costello, Principal Deputy Assistant Secretary of the Air Force (Acquisition)
12. Mr. Salvatori, Director, Capabilities Management Office
13. Mr. Bridges, Assistant Deputy Chief of Staff for Logistics, Engineering and Force Protection
14. Ms. Miller, Deputy Assistant Secretary of the Air Force for Installations
15. Mr. Geurts, Acquisition Executive, U.S. Special Operations Command
16. Ms. Nolta, Deputy Director, Air Force Staff

Additionally, all career status Air Force Tier 3 SES members not included in the above list are eligible to serve on the 2016 Performance Review Board and are hereby nominated for inclusion on an ad hoc basis in the event of absence(s).

FOR FURTHER INFORMATION CONTACT: Please direct any written comments or requests for information to Ms. Dawn Rayner, Deputy Director, Senior Executive Management, AF/DPS, 1040 Air Force Pentagon, Washington DC 20330–1040 (PH: 703–695–7677; or via email at *dawn.m.rayner.civ@mail.mil.*)

Bao-Anh Trinh,

Air Force Federal Register Liaison Officer.

[FR Doc. 2016–21056 Filed 9–2–16; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

United States Air Force

Notice of Intent To Prepare an Environmental Impact Statement (EIS) for the Housing Program at Wright-Patterson Air Force Base (AFB), OH

AGENCY: United States Air Force, Department of Defense.

ACTION: Notice of intent.

SUMMARY: The United States Air Force (Air Force) is issuing this notice to notify the public of its intent to prepare an Environmental Impact Statement (EIS) for the housing program at Wright-Patterson AFB. The EIS is being prepared in accordance with National Environmental Policy Act (NEPA) of 1969; 40 Code of Federal Regulations (CFR), Parts 1500–1508, the Council on Environmental Quality (CEQ) regulations for implementing NEPA; and the Air Force Environmental Impact Analysis Process (EIAP) [32 CFR part 989].

This notice also serves to invite early public and agency participation in determining the scope of environmental issues and alternatives to be analyzed in the EIS and to identify and eliminate from detailed study the issues which are not significant. To effectively define the full range of issues and concerns to be evaluated in the EIS, the Air Force is soliciting scoping comments from interested local, state and federal agencies, interested American Indian tribes, and interested members of the public. This NOI also serves to invite stakeholder participation and comment as part of the National Historic Preservation Act (NHPA) and in support and furtherance of the NHPA Section 106 consultation process.

Scoping comments may be submitted to the Air Force at the planned public scoping meetings and/or in writing.

DATES: The Air Force plans to hold two public scoping meetings from 5:30 p.m. to 8:30 p.m., on the dates and at the locations listed below.

- Monday, September 26, 2016: Fairborn High School Auditorium, 306 E. Whittier Avenue, Fairborn, OH 45324
- Tuesday, September 27, 2016: Fairborn High School Auditorium, 306 E. Whittier Avenue, Fairborn, OH 45324

The agenda for each scoping meeting is as follows:

- 5:30 p.m. to 6:30 p.m.—Open House and comment submission
- 6:30 p.m. to 7:00 p.m.—Air Force Presentation
- 7:00 p.m. to 8:30 p.m.—Open House and comment submission resumes

Local notices announcing scheduled dates, locations, and addresses for each meeting will be published in the Dayton Daily News, Fairborn Daily Herald, Beavercreek News Current, Xenia Daily Gazette and other publications a minimum of fifteen (15) days prior to each meeting.

Comments will be accepted at any time during the Environmental Impact Analysis Process (EIAP). However, to ensure the Air Force has sufficient time to consider public input in the preparation of the Draft EIS, scoping comments must be submitted no later than October 9, 2016.

ADDRESSES: Information on the Wright-Patterson AFB housing project can be accessed at the project Web site at *http://wpafbhousingeis.versar.com.* The project Web site can be used to submit scoping comments to the Air Force, or comments and inquiries may also be submitted by mail or email to the 88th Air Base Wing Public Affairs Office, 5135 Pearson Road, Bldg. 10, Room 253A, Wright-Patterson AFB, OH 45433 or by email at *88abw.pa@us.af.mil.*

SUPPLEMENTARY INFORMATION: Currently, 100 homes remain in the USAF inventory at WPAFB. These homes include ten homes on Yount Drive built in 1975, 89 homes built in 1934–1937 within a planned thematic landscape now managed as the Brick Quarters Historic District (BQHD), and the NRHP-eligible Foulois House constructed in 1874. WPAFB presently operates and maintains the BQHD and Foulois House under provisions of the National Historic Preservation Act (NHPA) Sections 106 and 110. Environmental studies and impact analysis will evaluate options for new construction, conveyance to a private developer, lease, and demolition of these last remaining government-owned homes. Public scoping meetings will be held to assist in identifying reasonable alternatives, potential impacts, and the relative significance of impacts to be analyzed in the EIS.

The purpose of the action is to provide housing that meets Air Force standards for key and essential (K&E) personnel and their dependents stationed at WPAFB. The need for this action stems from mission requirements, Department of Defense (DOD) policy, and the USAF's obligations under the NHPA and Executive Order (EO) 13287, Preserve America. At a minimum, this action must support the mission by providing residences for 30 K&E personnel and their dependents who are required to live on WPAFB. The current privatized housing inventory does not support these needs, as the homes are not of adequate square footage and are not proximate enough to K&E work locations to support the base's housing requirements for the identified K&E personnel.

The EIS will address concerns associated with modification, conveyance, lease, and/or demolition of historic homes within the BQHD. The EIS will analyze alternatives that could include military construction and continued government ownership, housing privatization of all or a portion of the homes, NHPA Section 111 Lease, reuse as temporary lodging facilities, demolition, and the No Action Alternative. Within the framework of these alternatives, the EIS will support Air Force decisions by identifying and evaluating potential impacts to land use, safety, noise, hazardous materials and solid waste, earth resources, water resources, air quality, transportation, cultural resources, biological resources, socioeconomics, and environmental justice.

The USAF intends to use the EIS process and documentation to aid in fulfilling its NHPA, Section 106 consultation requirements (36 CFR 800.8) particularly regarding public participation in the planning process associated with this EIS. In addition, extensive consultation under NHPA Sec. 106 is ongoing with the OHPO, ACHP and other interested parties. That consultation is expected to produce a Sec. 106 project Programmatic Agreement which will be executed prior to issuance of this EIS's Record of Decision (ROD).

Henry Williams,

Acting Air Force Federal Register Officer.

[FR Doc. 2016–21274 Filed 9–2–16; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2016–OS–0056]

National Environmental Policy Act Implementing Procedures

AGENCY: Defense Threat Reduction Agency/USSTRATCOM Center for Combating Weapons of Mass Destruction, Department of Defense.

ACTION: Final guidance.

SUMMARY: The Defense Threat Reduction Agency/USSTRATCOM Center for Combating Weapons of Mass Destruction (DTRA/SCC–WMD or the Agency) is issuing procedures to implement the National Environmental Policy Act (NEPA), Executive Order (E.O.) 11514, and Council on Environmental Quality (CEQ) regulations for implementing the procedural provisions of NEPA.

DATES: This final guidance is effective on September 6, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Sherry Davis, Director, Environment, Safety, and Occupational Health Department, at (703) 767–7122 or by email at *sherry.j.davis3.civ@mail.mil.*

SUPPLEMENTARY INFORMATION: On Thursday, May 5, 2016 (81 FR 27107–27122), the Department of Defense published proposed guidance titled "National Environmental Policy Act Implementing Procedures" for a 30-day public comment period. The public-comment period ended on June 6, 2016. No public comments were received.

Further administrative edits were made to the final guidance. References to "J4/8C" were changed to "J4/8", and references to the Environment, Safety, and Occupational Health (ESOH) Team Web site were removed throughout the final guidance.

DTRA/SCC–WMD is a combat support agency that counters weapons of mass destruction (WMD). DTRA/SCC–WMD keeps WMD out of the hands of terrorists and other enemies by locking down, monitoring, and destroying weapons and weapons-related material, assists with plans and responses to WMD events, and develops and delivers cutting-edge technologies to assist with these endeavors.

As a Department of Defense (DoD) agency, the DTRA/SCC–WMD does not own real property. Most agency actions typically occur on host military service installations or ranges, or other Federal agency properties. DTRA/SCC–WMD formerly relied upon host installation NEPA implementing procedures, including categorical exclusions to address potential environmental impacts of agency actions. With the issuance of CEQ guidance "Establishing, Applying, and Revising Categorical Exclusions under the National Environmental Policy Act" (Nov. 23, 2010) and after consulting with CEQ and other similar DoD components, DTRA/SCC–WMD determined the need to establish NEPA implementing procedures and categorical exclusions specific to DTRA/SCC–WMD projects and actions. The information assembled while developing categorical exclusions is described in the "DTRA/SCC–WMD Administrative Record for Supporting Categorical Exclusions" and is available on the DTRA/SCC–WMD Web site at: *http://www.dtra.mil/Home/NEPA.aspx.*

The categorical exclusions describe the categories of actions that DTRA/SCC–WMD determined to normally not individually or cumulatively have significant impact on the environment. These and the other implementing procedures will serve as the agency's guide for complying with the requirements of NEPA for DTRA/SCC–WMD actions.

The text of the complete DTRA/SCC–WMD NEPA implementing procedures can be found on the DTRA/SCC–WMD Web site at: *http://www.dtra.mil/Home/NEPA.aspx* and in this document.

Dated: August 31, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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Defense Threat Reduction Agency/ USSTRATCOM Center for Combating Weapons of Mass Destruction NEPA Implementing Procedures

1. Purpose

Pursuant to DTRA/SCC–WMD Instruction 4715.5, "Environmental Compliance" (Aug. 22, 2014), this guide identifies requirements and provides procedures for implementing the provisions of the National Environmental Policy Act (NEPA) in accordance with Council on Environmental Quality Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act, 40 CFR parts 1500–1508, and E.O. 12114, "Environmental Effects Abroad of Major Federal Actions" (Jan. 4, 1979). It supplements 40 CFR parts 1500–1508 and E.O. 12114 by establishing policy, responsibilities, and procedures for fully considering environmental consequences of proposed actions, preparing necessary documentation for actions with the potential for significant environmental impact, and demonstrating transparency in decision-making.

DTRA/SCC–WMD does not own real property or undertake projects or programs where actions are planned or funded by private applicants or other non-Federal entities. Therefore, this guide does not include provisions to account for such actions.

2. Applicability

The requirements and procedures of this guide apply to all entities of DTRA/SCC–WMD and its executing agents.

3. Policy

It is DTRA/SCC–WMD policy to:

(a) Integrate environmental consideration into all Agency/Center activities at the earliest possible planning stage, make decisions considering environmental consequences, assess a range of reasonable alternative actions, and take actions that protect, restore, and enhance the environment.

(b) Prepare all necessary documentation required under NEPA and 40 CFR parts 1500–1508 whenever acting as the proponent or lead agency for a proposed action that has the potential for significant environmental impact.

(c) Serve as a cooperating agency for activities in which DTRA/SCC–WMD participates but is not the proponent or lead agency and provide full cooperation and necessary technical expertise and documentation to the lead agency as requested.

(d) Use programmatic and tiered analyses, when possible, to eliminate redundancies in future project/program analyses, effectively evaluate cumulative environmental effects, and reduce mission delays.

(e) Periodically (at least every 7 years) review the effectiveness of its NEPA procedures including responsibilities, implementing procedures, and categorical exclusions (CATEXs), and when new information or circumstances warrant, review the currency of existing Programmatic Environmental Impact Statements (EISs) and Programmatic Environmental Assessments (EAs).

(f) Involve the public in preparing and executing its NEPA procedures, and publish NEPA implementing procedures, CATEXs, and other relevant NEPA documentation as appropriate on the DTRA/SCC–WMD public Web site.

(g) Prepare NEPA documentation and procedures that are written in plain language so that decision-makers and the public can readily understand them.

(h) To the fullest extent possible, integrate NEPA requirements with other environmental review and consultation requirements including, but not limited to, Clean Water Act, Clean Air Act, Endangered Species Act, National Historic Preservation Act, Resource Conservation and Recovery Act, and Comprehensive Environmental Response, Compensation, and Liability Act.

(i) Eliminate duplication with State and local procedures by providing for, as appropriate, joint planning processes and, where appropriate, joint preparation of NEPA reviews (analyses and documentation).

(j) Eliminate duplication with other Federal procedures by jointly preparing NEPA reviews, or adopting other agencies' EAs and EISs, or incorporating by reference material into an EA or EIS where appropriate.

(k) Comply with host installation NEPA requirements in addition to the requirements set forth in this guide. Equivalent host installation documentation may be used to satisfy DTRA/SCC–WMD documentation requirements.

4. Responsibilities

(a) Director, DTRA/SCC–WMD (J0)

The J0 has final approval and signature authority of EIS Records of Decision (RODs) generated by DTRA/SCC–WMD or its contractors. This authority may be delegated as deemed appropriate by the J0.

(b) Joint Director (JDIR), Acquisition, Finance, and Logistics (J4/8)

The JDIR, J4/8 monitors the effective implementation of these procedures through the Director, Environment, Safety, and Occupational Health (ESOH) Department (J4E) and hereby appoints the Director, J4E as the principal Agency/Center advisor on NEPA-related requirements.

(c) Director, J4E

The Director, J4E as the principal Agency advisor on NEPA-related requirements:

(1) Provides guidance to Project/Program Managers as necessary on the requirements in this guide and maintains direct oversight of the NEPA process.

(2) Reviews project proposals to determine NEPA applicability and requirements, and provides qualified personnel to support Project/Program Managers with NEPA compliance.

(3) Performs environmental compliance reviews of EISs/RODs, EAs/Findings of No Significant Impact (FONSIs), and Records of Environmental Consideration (RECs) generated by DTRA/SCC–WMD or its contractors and provides initial approval by signature as the compliance authority.

(4) When DTRA/SCC–WMD serves as a cooperating agency for activities in which it participates but is not the proponent or lead, reviews and approves NEPA documents as requested by the lead agency.

(5) Maintains an organized administrative record of all NEPA documents generated by DTRA/SCC–WMD or its contractors, including documentation supporting Agency/Center CATEXs.

(6) Represents DTRA/SCC–WMD in NEPA-related matters with external organizations.

(7) Ensures required NEPA mitigation measures are documented in the administrative record, performed, and monitored.

(d) Office of the General Counsel (J0GC)

The J0GC provides a legal review of EISs, RODs, EAs, and FONSIs generated by DTRA/SCC–WMD or its contractors.

(e) Governmental and Public Affairs Office (J0XG)

The J0XG:

(1) Assists Project/Program Managers with engaging the public for scoping meetings, accepting comments, providing adjudications, outreach efforts, and other related interactions.

(2) Coordinates the public release of DTRA/SCC–WMD NEPA documentation using various mediums including local newspapers, DTRA/SCC–WMD's public Web sites, and the **Federal Register** (FR).

(3) Approves, signs, and publishes Notices of Intent (NOI) and Notices of Availability (NOA).

(f) Directorate JDIRs/Staff Office Chiefs/ SCC–WMD Divisions

The Directorate JDIRS/Staff Office Chiefs/SCC–WMD Divisions:

(1) Integrate environmental considerations early in the planning stages of all Directorate/Staff Office/ SCC–WMD Division activities with adequate time to ensure NEPA requirements can be met.

(2) Provide project proposals to the Director, J4E for any planned DTRA/ SCC–WMD activity with potential for environmental impact.

(3) Provide necessary funding to satisfy NEPA requirements for Directorate/Staff Office/SCC–WMD Division activities subject to compliance.

5. Environmental Planning & Analysis

(a) Record of Environmental Review

(1) A flowchart outlining the general NEPA process can be found in Appendix A.

(2) As early in the planning process as possible, the Project/Program Manager of a proposed action must provide to the J4E a project proposal by completing the top section of a REC (found in Appendix C) with information regarding the scope of the activity.

(3) A REC is used to document the environmental analysis for an activity. The REC could indicate that a CATEX applies and there are no extraordinary circumstances requiring further analysis; that the activity is covered under a previous analysis (EA/EIS) and further analysis is not required, or that additional analysis is needed (EA/EIS).

(4) Based on conclusions of the initial environmental analysis, additional analysis may be required. Project/ Program Managers must also comply with other applicable statutory or regulatory requirements set out in DTRA/SCC–WMD Instruction 4715.5, including but not limited to environmental permits, consultations, and approvals such as those required for actions affecting federally-listed threatened or endangered species or their designated critical habitat, historic and cultural preservation, safe drinking water requirements, as well as other applicable state, DoD, or local regulatory requirements.

(b) Categorical Exclusion (CATEX)

(1) A CATEX is a category of Agency/ Center actions which have been determined to normally not individually or cumulatively have significant impact on the environment and therefore neither an EA nor EIS is required. Project/Program Managers may use a CATEX for a proposed action with approval from the J4E when there are no extraordinary circumstances that warrant further analysis in an EA or EIS. (i) A list of approved CATEXs can be found in Appendix B. DTRA/SCC–WMD must not use a CATEX that is not listed in the appendix. Proposals for additional CATEXs must be submitted to and approved by the J4E and CEQ, be reviewed through a public comment period, and be supported by appropriate substantiating documentation such as an EA/FONSI, impact demonstration projects, or information from professional staff, expert opinions, and scientific analyses. (ii) Extraordinary circumstances are also listed in Appendix B following the list of CATEXs.

(2) If a CATEX applies, the J4E will document use of the specific CATEX on the REC, and the action may proceed. The REC should document any determination and conclusion where the issue of whether an extraordinary circumstance requires further review has been resolved. This determination can be made using current information and expertise, if available and adequate, or can be derived through conversation, as long as the basis for the determination is included in the REC. Copies of appropriate interagency correspondence can be attached to the REC. Example conclusions regarding screening criteria are as follows: (i) "U.S. Fish and Wildlife Service concurred in informal coordination that endangered or threatened species will not be adversely affected." (ii) "Corps of Engineers determined action is covered by nationwide general permit." (iii) "State Historic Preservation Officer concurred with action." (iv) "State Department of Natural Resources concurred that no adverse effects to state sensitive species are expected."

(3) If a CATEX does not apply, either by not including the proposed action or due to extraordinary circumstances, and the action is not covered under an existing document, then an EA or EIS must be prepared unless the proposed action is not further considered.

(4) To use a CATEX, the proponent must satisfy the following three screening conditions: (i) The action has not been segmented. Determine that the proposed action has not been segmented to meet the definition of a CATEX and fits within the category of actions described in the CATEX. Segmentation can occur when an action is broken down into small parts in order to avoid the appearance of significance of the total action. An action can be too narrowly defined, minimizing potential impacts in an effort to avoid a higher level of NEPA documentation. The scope of an action must include the consideration of connected actions, and the effects when applying extraordinary circumstances must consider cumulative impacts. (ii) No exceptional circumstances exist. Determine if the action involves extraordinary circumstances that would preclude the use of a CATEX (see Appendix B). (iii) One CATEX encompasses the proposed action. Identify a CATEX that encompasses the proposed action (see Appendix B). If multiple CATEXs could be applicable, proceed when it is clear that the entire proposed action is covered by one CATEX. Any limitation in any potentially applicable CATEX should be considered when determining whether it is appropriate to proceed without further analysis in an EA or EIS.

(c) Environmental Assessment (EA)

(1) An EA is a concise public document used to provide sufficient evidence and analysis for determining whether to prepare an EIS or FONSI or to comply with NEPA when an EIS is not necessary.

(2) The EA must include, at a minimum, the following: (i) Cover page, which identifies the proposed action and the geographic location. (ii) Purpose and need for the proposed action or activity. (iii) Description of the proposed action with sufficient detail in terms that are understandable to readers that are not familiar with DTRA/SCC–WMD activities. (iv) Discussion of alternative actions considered, including the preferred action and a "no action" alternative. There is no requirement for a specific number of alternatives or a specific range of alternatives to be included in an EA. An EA may limit the range of alternatives

to the proposed action and no action when there are no unresolved conflicts concerning alternative uses of available resources. For alternatives considered but eliminated from further study, the EA should briefly explain why these were eliminated. (v) Description of the affected environment. (vi) Analysis of the potential environmental impacts of the proposed action and alternatives. The EA must discuss, in comparative form, the reasonably foreseeable environmental impacts of the proposed action, the no action alternative, and any other reasonable alternatives necessary to address unresolved conflicts concerning the alternative use of resources. The discussion of environmental impacts must focus on substantive issues and provide sufficient evidence and analysis to support a FONSI unless a determination to prepare an EIS is made. (vii) Identification of any permits, licenses, approvals, reviews, or applicable special purpose laws. Although the NEPA process does not preclude separate compliance with these other requirements, DTRA/SCC–WMD will integrate applicable environmental review, consultation, and public involvement requirements under special purpose laws and requirements into its NEPA planning and documentation to reduce paperwork and delay. (viii) List of preparers, agencies, and persons consulted. (ix) Signature of the preparer(s) and the Director, J4E. (x) References and appendices. The appendices may include: (A) References that support statements and conclusions in the body of the EA, including methodologies used. Proper citations and, when available, hyperlinks to reference materials should be provided; (B) Evidence of coordination or required consultation with affected Federal, state, tribal, and local officials and copies or a summary of their comments or recommendations and the responses to such comments and recommendations; and (C) A summary of public involvement, including a summary of issues raised at any public hearing or public meeting.

(3) The analysis of potential environmental impacts (item (c)(2)(vi) above) will include an assessment of the direct, indirect, and cumulative impacts that can reasonably be expected from taking the proposed action or alternatives, and the analysis should address substantive comments raised by interested Federal agencies, non-Federal agencies, and private parties. (i) When direct or indirect impacts exist, the EA must consider cumulative impacts. Cumulative impacts are impacts on the environment resulting from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions. (ii) Actions by Federal agencies, non-Federal agencies, and private parties must be included when considering cumulative impacts.

(4) DTRA/SCC–WMD must coordinate, as appropriate, preparation of the EA with other agencies (Federal, state, local, or tribal governments) when the action involves resources they manage or protect, and will invite agencies with jurisdiction by law or with special expertise to participate as cooperating agencies. (i) Agencies with jurisdiction by law are those with the authority to grant permits for implementing actions, approve or veto portions of the proposed action, or finance a portion of the proposed action. Federal agencies with jurisdiction by law must be a cooperating agency. Non-federal agencies may be invited. (ii) Agencies with special expertise are those that have the expertise needed to help meet a statutory responsibility, to carry out in part the DTRA/SCC–WMD mission, or in the proposed actions' relationship to the objectives of regional, state, or local land use plans, policies, and controls. Federal and non-federal agencies may be invited.

(5) DTRA/SCC–WMD must involve the public, to the extent practicable, in preparing EAs. (i) The appropriate level of involvement will vary based on the proposed action. A public scoping meeting, as described in 40 CFR 1501.7, is not required for an EA but is optional. Scoping can be particularly useful when an EA deals with uncertainty or controversy regarding potential conflicts over the use of resources or the environmental impacts of the proposed actions. The scoping process can provide a transparent way to identify environmental issues, focusing the analysis on the most pertinent issues and impacts. (ii) A draft EA should be circulated for 30 days of public comment and, if applicable, with the unsigned proposed FONSI, per paragraph (d)(7) of the FONSI provisions below. The length of comment period may be adjusted based on mission requirements.

(6) DTRA/SCC–WMD will use the conclusions of an EA to determine whether to issue a FONSI or an NOI to prepare an EIS (found in Appendix D).

(d) Finding of No Significant Impact (FONSI)

(1) A FONSI is a document that briefly presents the reasons why a proposed action will not have a significant effect on the human environment and for which an EIS therefore will not be prepared. It must include the EA or a summary of it and note any other environmental documents related to it.

(2) Mitigated FONSIs are appropriate where the J4E and Project/Program Manager, or other decision-maker for the project/program determine that mitigation measures can reduce potentially significant adverse impacts below the level of significance. These mitigation measures may be used to support a FONSI, provided that: (i) The relevant areas of environmental concern are identified in the EA; (ii) The EA supports the Agency's determination that the potential impacts, including the impacts of any mitigation commitments, will be insignificant; and (iii) The Agency has identified mitigation measures that will be sufficient to reduce potential impacts below applicable significance thresholds and has ensured commitments to implement these measures.

(3) Mitigation that is used to support a mitigated FONSI must be included as a condition of project approval. In these cases, if DTRA/SCC–WMD's decision to act is not otherwise evidenced by a final decision document such as a rule, license, or approval, the J4E and the Project Manager or other decision-maker for the project/program must document the decision in the conclusion of the FONSI. The decision must identify those mitigation measures DTRA/SCC–WMD is adopting and identify any monitoring and enforcement program applicable to such measures (see Section 6: Mitigation and Monitoring).

(4) A FONSI or Mitigated FONSI must document, in plain writing, the reasons why an action, not otherwise categorically excluded, would not have a significant impact on the human environment. The FONSI documents the basis for the determination that the proposed action would not have significant environmental impacts and the decision to implement the proposed action. The FONSI may be attached to an EA, or the EA and FONSI may be combined into a single document. If the FONSI is attached or combined with the EA, it need not repeat the discussion in the EA. If the FONSI is not attached or combined with the EA, the FONSI must include a summary of the EA and note any other environmental documents related to it. The FONSI must: (i) Briefly describe the proposed action, the purpose and need, and the alternatives considered (including the no action alternative), and assess and document all relevant matters necessary to support the conclusion that the proposed action would not significantly affect the

quality of the human environment; (ii) Determine the proposed action's consistency or inconsistency with community planning, and document the basis for the determination; (iii) Present any mitigation measures that are a condition of project approval. The FONSI should also reflect coordination of mitigation commitments (including any applicable monitoring program) with, and consent and commitment from, those entities with the authority to implement specific mitigation measures committed to in the FONSI; and (iv) Reflect compliance with all applicable environmental requirements, including interagency and intergovernmental coordination and consultation, public involvement, and documentation requirements. Findings and determinations required under special purpose laws and requirements, regulations, and orders, if not made in the EA, must be included in the FONSI. (v) If the FONSI is prepared following adoption of all or part of another agency's NEPA document, the FONSI must identify the part(s) of the document being adopted and include documentation of DTRA/SCC–WMD's independent evaluation of the document.

(5) All FONSIs must include the following approval statement: After careful and thorough consideration of the facts contained herein, the undersigned finds that the proposed Federal action is consistent with existing national environmental policies and objectives as set forth in Section 101 of NEPA and other applicable environmental requirements and will not significantly affect the quality of the human environment.

APPROVED: ____________________

DATE: ____________________

(6) Following preparation of the FONSI, the Project/Program Manager reviews and signs the FONSI. Issuance of a FONSI signifies that DTRA/SCC–WMD will not prepare an EIS and has completed the NEPA process for the proposed action. Following the approval of a FONSI, the Project/Program Manager may decide whether to take or approve the proposed action. Mitigation measures that were made as a condition of approval of the FONSI must be incorporated in the decision to implement the action.

(7) The J0XG in coordination with the Project/Program Manager will publish an NOA (found in Appendix E) with local media to open a 30-day public comment period for the final draft EA and unsigned proposed FONSI. For actions with national interest, J0XG shall also publish the NOA in the FR. The length of comment period may be adjusted based on mission requirements.

(8) After closure of the public comment period, the Project/Program Manager in coordination with the J4E will adjudicate the comments received and update the EA as necessary. The Project/Program Manager in coordination with the J4E will decide to prepare an EIS, or terminate the proposed action.

(9) Upon completing the adjudication, the final FONSI will be signed by the J4E and Project/Program Manager or other decision-maker for the project/program, and the action may proceed.

(10) The J0XG will make the final EA and signed FONSI available to the public and post on DTRA/SCC–WMD's public Web site. (i) A copy of the FONSI and EA should be sent to reviewing agencies and organizations or individuals who made substantive comments or specifically requested copies. (ii) When a project involves a resource protected under a special purpose law or requirement, or other directive, the J0XG will send a signed copy of the FONSI and the EA supporting it to the agency(ies) with whom DTRA/SCC–WMD consulted to comply with the applicable law or directive and to any party requesting copies of those documents.

(e) Environmental Impact Statement (EIS)

(1) When a proposed action has the potential for significant environmental impact or when an EA does not result in a FONSI, an EIS will be prepared to examine the potential impacts of the proposed action, reasonable alternatives, and measures to mitigate those effects.

(2) Prior to preparing an EIS, the Project/Program Manager in coordination with J0XG will publish an NOI (Appendix D) in the FR to initiate preparation of the EIS. (i) The NOI includes an overview of the proposed action, any reasonable alternatives being considered (including no action), and known potential environmental impacts associated with the action. If the NOI is also used to satisfy public notice and comment requirements of other environmental requirements in addition to NEPA that are applicable to the proposed action, the NOI should include a statement to that effect with a reference to the applicable laws, regulations, or Executive Orders. (ii) The NOI will also identify a DTRA/SCC–WMD point of contact who can provide additional information about the action and to whom comments should be sent. (iii) There will be a public scoping period of 30 days from the date of publication of the NOI in the FR to allow other interested agencies and the public to provide input and comments. If a scoping meeting is planned and sufficient information is available at the time of the NOI, the NOI should also announce the meeting, including the meeting time and location, and other appropriate information such as availability of a scoping document.

(3) The Project/Program Manager must host a public EIS scoping meeting to identify the range of actions, alternatives, and impacts to consider for analysis. Scoping is a required part of the EIS process. Scoping is an early and open process for determining the scope of issues to be addressed in the EIS and identifying the significant issues related to a proposed action. The Project/Program Manager shall tailor the scoping processes to match the complexity of the proposal. (i) DTRA/SCC–WMD representatives must include at a minimum the Project/Program Manager, the J4E, and program subject matter experts. The Project/Program Manager will also invite interested members of the public and representatives from cooperating organizations, and may include other participants as necessary. (ii) Scoping serves additional purposes such as identifying those issues that do not require detailed analysis or that have been covered by prior environmental review, setting the temporal and geographic boundaries of the EIS, determining reasonable alternatives, and identifying available technical information. (iii) The Project/Program Manager with assistance from the J4E must take the lead in the scoping process, inviting the participation of potentially affected Federal, state, and local agencies, any potentially affected tribes, and other interested persons (including those who might oppose the proposed action).

(4) An EIS must include the following components presented in the standard EIS format in accordance with 40 CFR parts 1500–1508: (i) A cover page that includes: (A) A list of the responsible lead and cooperating agencies (identifying the lead agency); (B) The title of the proposed action together with the state(s) and county(ies) where the action is located; (C) The name, address, and telephone number of the responsible DTRA/SCC–WMD official; (D) The designation of the statement as draft, final, or supplement; (E) A one paragraph abstract of the EIS; and (F) For draft EISs, a statement that this EIS is submitted for review pursuant to applicable public law requirements. (ii)

An executive summary that adequately and accurately summarizes the EIS. The summary describes the proposed action, stresses the major conclusions, areas of controversy (including issues raised by agencies and the public), and the issues to be resolved (including the choice among alternatives). It also discusses major environmental considerations and how these have been addressed, summarizes the analysis of alternatives, and identifies the agency preferred alternative. It discusses mitigation measures and any monitoring. (iii) A table of contents that lists the chapters and exhibits (including figures, maps, and tables) presented throughout the EIS. It will also list any appendices, acronym list, glossary, references, and index. (iv) A Purpose and Need section that briefly describes the underlying purpose and need for the Federal action. It presents the problem being addressed and describes what DTRA/SCC–WMD is trying to achieve with the proposed action. It provides the parameters for defining a reasonable range of alternatives to be considered. The purpose and need for the proposed action must be clearly explained and stated in terms that are understandable to individuals who are not familiar with DTRA/SCC–WMD activities. Where appropriate, the responsible DTRA/SCC–WMD official should initiate early coordination with cooperating agencies in developing purpose and need. (v) An Alternatives section that includes the proposed action. This section is the heart of the EIS. It presents a comparative analysis of the no action alternative, the proposed action, and other reasonable alternatives to fulfill the purpose and need for the action, to sharply define the issues, and provide a clear basis for choice among alternatives by the approving official. Whether a proposed alternative is reasonable depends, in large part, upon the extent to which it meets the purpose and need for the proposed action. Reasonable alternatives not within the jurisdiction of the lead agency should be considered. DTRA/SCC–WMD may include alternatives proposed by the public or another agency. However, they must meet the basic criteria for any alternative: It must be reasonable, feasible, and achieve the project's purpose. The extent of active participation in the NEPA process by the proponent of the alternative also bears on the extent to which a preferred alternative deserves consideration. Charts, graphs, and figures, if appropriate, may aid in understanding the alternatives. To provide a clear basis of choice among the alternatives, graphic or tabular presentation of the comparative impact is recommended. This section also presents a brief discussion of alternatives that were not considered for detailed analysis (*e.g.,* because they do not meet the purpose and need for the proposed action). The draft EIS must identify the preferred alternative or alternatives, if one or more exists at the time the draft EIS is issued. The final EIS must specifically and individually identify the preferred alternative. Criteria other than those included in the affected environment and environmental consequences sections of the EIS may be applied to identify the preferred alternative. Although CEQ encourages Federal agencies to identify the environmentally-preferred alternatives in the EIS, the CEQ Regulations do not require that discussion until the ROD. (vi) An affected environment section that describes the environmental conditions of the potentially affected geographic area or areas. The discussion of the affected environment should be no longer than is necessary. It should include detailed discussion of only those environmental impact categories affected by the proposed action or any reasonable alternatives to demonstrate the likely impacts; data and analyses should be presented in detail commensurate with the importance of the impact. To ensure that this section emphasizes the important aspects of the impacts on the environment, the discussion should summarize and incorporate by reference information or analysis that is reasonably available to the public. This section may include the following, if appropriate: (A) Location map, vicinity map, project layout plan, and photographs; (B) Existing and planned land uses and zoning, including: industrial and commercial growth characteristics in the affected vicinity; affected residential areas, schools, places of outdoor assemblies of persons, churches, and hospitals; public parks, wildlife and waterfowl refuges; federally listed or proposed candidate, threatened, or endangered species or federally designated or proposed critical habitat; wetlands; national and state forests; floodplains; farmlands; coastal zones, coastal barriers, or coral reefs; recreation areas; wilderness areas; wild and scenic rivers; Native American cultural sites, and historic and archeological sites eligible for or listed on the National Register of Historic Places; (C) State or local jurisdictions affected by the proposed action or any reasonable alternatives; (D) Population estimates and other relevant demographic information for the affected environment, including a census map where appropriate; and (E) Past, present, and reasonably foreseeable future actions, whether Federal or non-Federal, including related or connected actions to show the cumulative effects of these actions on the affected environment. (vii) An environmental consequences section, which forms the scientific and analytical basis for comparing the proposed action, the no action alternative, and other alternatives retained for detailed analysis. (A) The discussion of environmental consequences will include the environmental impacts of the alternatives including the proposed action; any adverse environmental impacts that cannot be avoided should the proposed action or any of the reasonable alternatives be implemented; the relationship between short-term uses of man's environment and the maintenance and enhancement of long-term productivity; any irreversible or irretrievable commitments of resources that would be involved in the proposed action or any reasonable alternatives should they be implemented; and mitigation. It must include considerations of direct, indirect, and cumulative impacts and their significance and possible conflicts with the objectives of Federal, regional, state, tribal, and local land use plans, policies, and controls for the area concerned and other unresolved conflicts. To avoid excessive length, the environmental consequences section may incorporate by reference background data to support the impacts analysis. 40 CFR 1502.22 sets forth requirements for addressing situations in which information for assessing reasonably foreseeable significant adverse impacts is incomplete or unavailable. (B) Specific environmental impact categories must be discussed to the level of detail necessary to support the comparisons of impacts of each alternative retained for detailed analysis, including the no action alternative. The section should include the information required to demonstrate compliance with other applicable requirements and should identify any permits, licenses, other approvals, or reviews that apply to the proposed action or any reasonable alternatives, and indicate any known problems with obtaining them. This section should also provide the status of any interagency or intergovernmental consultation required, for example, under the National Historic Preservation Act, 16 U.S.C. 470–470x–6, the Endangered Species Act, 16 U.S.C. 1531–1544, the Coastal Zone

Management Act, 16 U.S.C. 1451–1466, the American Indian Religious Freedom Act, 42 U.S.C. 1996, Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, 63 **Federal Register** 27655 (May 14, 1998), the Wild and Scenic Rivers Act, 16 U.S.C. 1271–1287, and the Fish and Wildlife Coordination Act, 16 U.S.C. 661–667d. (viii) An EIS must describe mitigation measures considered or planned to minimize harm from the proposed action and reasonable alternatives. The EIS must discuss mitigation in sufficient detail to disclose that the environmental consequences have been fairly evaluated. Mitigation incorporated into project design must be clearly described in the proposed action and any reasonable alternatives. Environmental impacts resulting from mitigation must be considered in the EIS, when applicable. (A) The following types of mitigation measures should be considered: design and construction actions to avoid or reduce impacts; management actions that reduce impacts during operation of the facility; and replacement, restoration (reuse, conservation, preservation, etc.), and compensation measures. (B) Electronic data collection, tracking, and analysis may be useful in the consideration of appropriate mitigation measures. The DTRA/SCC–WMD ESOH Management System may also be used for tracking and monitoring mitigation commitments. (C) Mitigation and other conditions established in the EIS, or during review of the EIS, and that are committed to in the ROD, must be implemented by DTRA/SCC–WMD or another appropriate entity with authority to implement the identified mitigation measures or other conditions. DTRA/SCC–WMD ensures implementation of such mitigation measures through special conditions, funding agreements, contract specifications, directives, other review or implementation procedures, and other appropriate follow-up actions in accordance with 40 CFR parts 1500–1508. (ix) The EIS must list the preparers of the NEPA document, including the names, and qualifications (*e.g.,* expertise experience, professional disciplines) of DTRA/SCC–WMD staff that were primarily responsible for preparing the EIS or significant background material, and contractors who assisted in preparing the EIS or associated environmental studies. (x) The EIS must contain a list of agencies, organizations, and persons to whom copies of the EIS are sent. This list is included for reference and to demonstrate that the EIS is being circulated, and thus, that the public review process is being followed. (xi) An index that reflects the key terms used throughout the EIS for easy reference. The index must include page numbers for each reference. (xii) An EIS must include appendices, if necessary. This section consists of material that substantiates any analysis that is fundamental to the EIS, but would substantially contribute to the length of the EIS or detract from the document's readability, if included in the body of the EIS. This section should contain information about formal and informal consultation conducted and related agreement documents prepared, pursuant to other special purpose laws and requirements. (xiii) The Final EIS must assess and respond to comments received on the draft EIS. (xiv) If applicable, the EIS may include footnotes. Footnotes include the title, author, date of document, and page(s) relied upon for sources used.

(5) An EIS may not include any final decisions regarding the Agency/Center's course of action.

(6) The J4E must file the draft EIS with the United States Environmental Protection Agency (EPA) through the e-NEPA electronic filing system at: *http://www.epa.gov/oecaerth/nepa/submiteis/index.html.* As part of the draft EIS filing process, the EPA will issue an NOA in the FR to open a 45-day comment period for the public, federally recognized tribes, or other interested Federal, state, and local agencies. This starts the official comment period for the draft EIS. The J0XG shall also publish an NOA (Appendix E) in a local daily newspaper on the same day that EPA's NOA is published. DTRA/SCC–WMD should send a press release to local media and, if the EIS is national in scope, to national media outlets. DTRA/SCC–WMD must notify EPA if it approves an extension of the public comment period so that EPA may provide an update in its FR notice. (i) The draft EIS should be available at local libraries or similar public depositories. Material used in developing or referenced in the draft EIS must be available for review at the appropriate DTRA/SCC–WMD office(s) or at a designated location. Upon request, copies of the draft EIS must be made available to the public without charge to the extent practical or at a reduced charge, which is not more than the actual cost of reproducing copies. The draft EIS may also be placed on the Internet and/or copies may be made available in digital form. (ii) The J0XG should use the following standard language in press releases and notices announcing the draft EIS's availability for comment and any public meetings or hearing(s) associated with the proposed project: DTRA/SCC–WMD encourages all interested parties to provide comments concerning the scope and content of the draft EIS. Comments should be as specific as possible and address the analysis of potential environmental impacts and the adequacy of the proposed action or merits of alternatives and the mitigation being considered. Reviewers should organize their participation so that it is meaningful and makes the agency aware of the reviewer's interests and concerns using quotations and other specific references to the text of the draft EIS and related documents. Matters that could have been raised with specificity during the comment period on the draft EIS may not be considered if they are raised for the first time later in the decision process. This commenting procedure is intended to ensure that substantive comments and concerns are made available to DTRA/SCC–WMD in a timely manner so that DTRA/SCC–WMD has an opportunity to address them. Before including your address, phone number, email address, or other personal identifying information in your comment, be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so.

(7) DTRA/SCC–WMD should hold public meetings or hearings on the draft EIS, when appropriate. If DTRA/SCC–WMD conducts a public meeting or hearing for the purpose of obtaining public comment on a draft EIS, DTRA/SCC–WMD should ensure that the draft document is available for public review at least 15 days before the event occurs. (i) The Project/Program Manager must request comments on the draft EIS from appropriate Federal, state, and local agencies and from tribes when the impacts may be on a reservation or affect tribal interests. (ii) Draft EISs must be coordinated with the appropriate regional offices of other Federal agencies having jurisdiction by law or special expertise, appropriate state and local agencies including cooperating agencies, affected cities and counties, and others known to have an interest in the action, and appropriate tribal governments when the impacts may affect tribal interests.

(8) After closure of the comment period, the Project/Program Manager and the J4E will adjudicate the comments received by considering the

input or concern and documenting a response, update the EIS as necessary, and complete an ROD (found in Appendix F) or terminate the proposed action. (i) DTRA/SCC–WMD must take into consideration all comments received on the draft EIS and comments recorded during public meetings or hearings, and respond to the substantive comments in the final EIS. All substantive comments received on the draft EIS (or summaries where the comments are voluminous) must be attached to the final EIS. Comments must be responded to in one or more of the following ways: (A) Written into the text of the final EIS; (B) Stated in an errata sheet attached to the final EIS; or (C) Included or summarized and responded to in an attachment to the final EIS, and if voluminous, may be compiled in a separate supplemental volume for reference. (ii) DTRA/SCC–WMD may, subject to the conditions set forth below, attach errata sheets to the draft EIS. If the modifications to the draft EIS in response to comments are minor and are confined to factual corrections or explanations of why the comments do not warrant additional agency response, then only the comments, responses, and errata sheets need to be circulated and the draft EIS and errata sheets may be filed as the final EIS as set out in 40 CFR1503.4(c). Use of errata sheets is subject to the condition that the errata sheets: (A) Cite the sources, authorities, or reasons that support the position of DTRA/SCC–WMD; and (B) If appropriate, indicate the circumstances that would trigger agency reappraisal or further response.

(9) The cover page or summary of the final EIS or a draft EIS with errata sheets in lieu of a final EIS must include the following declaration language below. After careful and thorough consideration of the information contained herein and following consideration of the views of those Federal agencies having jurisdiction by law or special expertise with respect to the environmental impacts described, the undersigned finds that the proposed Federal action is consistent with existing national environmental policies and objectives as set forth in Section 101(a) of the National Environmental Policy Act of 1969.

(10) Other required environmental findings and conclusions must be included in the summary, if not included in the body or at the end of the EIS.

(11) The final EIS must be reviewed and approved by the Project/Program Manager and the J4E prior to generating an ROD.

(12) The J4E will file the final EIS with the EPA through the e-NEPA electronic filing system at: *http://www.epa.gov/oecaerth/nepa/submiteis/index.html.* The EPA will issue an NOA for the final EIS in the FR. The Project/Program Manager may request that the J0XG also publish a more detailed availability notice in the FR, but the DTRA/SCC–WMD notice cannot be substituted for the EPA FR notice. The final EIS must be sent to: (i) The appropriate regional office of EPA; (ii) Any relevant DoD officials; (iii) Each Federal, state, and local agency, tribe, and private organization that made substantive comments on the draft EIS and to individuals who requested a copy of the final EIS or who made substantive comments on the draft EIS (one copy each); (iv) DOE headquarters for projects having major energy-related consequences (one copy); and (v) The appropriate state-designated single point of contact (or specific agency contacts when states have not designated a single contact point), unless otherwise designated by the governor (adequate number of copies, which varies by state). (vi) Additional copies must be sent to accessible locations to be made available to the general public such as state, metropolitan, and local public libraries to facilitate accessibility. The final EIS, comments received, and supporting documents must be made available to the public without charge to the fullest extent practical or at a reduced charge, which is not more than the actual cost of reproducing copies, at appropriate agency office(s) or at a designated location.

(13) DTRA/SCC–WMD must wait a minimum of 30 days after the EPA NOA of the final EIS is published in the FR (and at least 90 days after filing of the draft EIS) before making a decision on the proposed action and issuing an ROD. The 30-day period provides time for the decision-maker to consider the final EIS and other pertinent information and make a decision; it is not for receiving public comments unless DTRA/SCC–WMD requests comments on the final EIS. At the conclusion of the 30-day waiting period, the J0 may issue the final decision in an ROD and implementation of the selected action may begin. (i) When DTRA/SCC–WMD is the lead Federal agency, the EPA, upon a showing by another Federal agency of compelling reasons of national policy, may extend prescribed periods up to 30 days, but no longer than 30 days without the permission of DTRA/SCC–WMD. The Project/Program Manager may also extend the waiting period or request the EPA to reduce this period for compelling reasons of national policy. The 90-day waiting period after the NOA of the draft EIS cannot be altered by the EPA. (ii) If DTRA/SCC–WMD unilaterally approves an overall extension of a comment period, the EPA must be notified so that the EPA may provide an update in its FR notice.

(14) Under certain circumstances, DTRA/SCC–WMD may choose to terminate an EIS. This could occur, for example, when a proponent has decided not to go forward with the action or it is determined to be no longer needed. DTRA/SCC–WMD may also terminate an EIS and revert to an EA if the environmental analysis shows that there would not be significant impacts from the project. DTRA/SCC–WMD will provide notice of the determination to no longer conduct an EIS that is issued in a manner comparable to the publication and distribution used for the NOI to prepare the EIS. The notice should cite the date of the original NOI to prepare an EIS and state the reasons why DTRA/SCC–WMD has chosen to terminate the EIS.

(f) Record of Decision (ROD)

(1) The ROD (Appendix F) will state DTRA/SCC–WMD's final decision on which action will be taken. The ROD may be prepared after the time periods outlined in the EIS section above. The Project/Program Manager and the J4E must provide concurrence on the ROD before submitting to the J0 for approval. Supplements to final EISs may be necessary (see Section (7)(b) Supplemental EAs/EISs) and must be reviewed and approved in the same manner as the original document, and a new draft ROD should be prepared, circulated, and approved. (i) DTRA/SCC–WMD may select any alternative within the range of alternatives analyzed in the final EIS. The selected alternative may be an alternative other than the agency's preferred alternative or the environmentally-preferred alternative. The selected action may not be implemented until the J0 has approved and signed the ROD. (ii) If DTRA/SCC–WMD selects an alternative other than the preferred alternative in the final EIS that involves special purpose laws and requirements, such as those related to Section 4(f) land, federally listed endangered species, wetlands, or historic sites, the Agency must first complete any required permit, evaluation, consultation, or other approval requirement prior to taking the action.

(2) DTRA/SCC–WMD must provide public notice of availability of the ROD

through appropriate means as required by 40 CFR 1506.6(b). Such means may include publication in the FR, other media, and on the Internet, although publication in the FR is only required for actions with effects of national concern.

(3) The ROD must: (i) Present DTRA/SCC–WMD's decision on the proposed action, and identify and discuss all factors, including any essential considerations of national policy, that were balanced by the Agency in making its decision and state how those considerations entered into the decision; (ii) Identify all alternatives DTRA/SCC–WMD considered and which alternative(s) is/are considered to be environmentally-preferable. DTRA/SCC–WMD may discuss preferences among alternatives based on relevant factors including economic and technical considerations, and agency statutory missions; (iii) Identify any mitigation measure(s) committed to as part of the decision and summarize any applicable mitigation monitoring and enforcement program. This must include any mitigation measure that was committed to as a condition of the approval of the final EIS; (iv) State whether all practicable means to avoid or minimize environmental harm from the selected alternatives have been adopted, and if not, why; and (v) Include any findings required by Executive Order, regulation, or special purpose law or requirement (*e.g.,* wetlands, Section 4(f), etc.).

(4) As necessary, the ROD can be used to clarify and respond to issues raised on the final EIS when those issues do not require supplementation of the final EIS.

(5) If the ROD is prepared following adoption of all or part of another agency's NEPA document (see Section (7)(c) Adoption of EAs/EISs), the ROD must incorporate by reference the part(s) of the document being adopted and include documentation of DTRA/SCC–WMD's independent evaluation of the document.

(6) The ROD must be signed by the J0 or delegated authority and posted with the EIS on the DTRA/SCC–WMD public Web site by the J0XG.

(7) The action must proceed no less than 30 days after the EPA has published the NOA for the final EIS (see paragraph (5)(e)(13)).

6. Mitigation and Monitoring

(a) DTRA/SCC–WMD must indicate whether mitigation measures will be implemented for the action selected in either a FONSI or ROD, the commitments the Agency/Center considered and selected, and who will be responsible for implementing, funding, and monitoring the mitigation measures.

(b) If the J4E and the Project Manager or other decision-maker for the project/program determine that a mitigation measure stipulated in a FONSI has not been implemented or the implemented mitigation is failing to mitigate environmental impacts as predicted, and as a result a significant impact may occur, the J4E and the Project Manager or other decision-maker for the project/program must initiate the EIS process by issuing an NOI to prepare an EIS if there remains discretionary DTRA/SCC–WMD action to be taken related to the project.

(c) When possible, the Project/Program Manager should include the cost of mitigation as a line item in the budget for a proposed project/program. DTRA/SCC–WMD ensures implementation of such mitigation measures through memorandums of agreement, funding agreements, contract specifications, directives, other review or implementation procedures, and other appropriate follow-up actions.

(d) DTRA/SCC–WMD may "mitigate to insignificance" potentially significant environmental impacts found during preparation of an EA instead of preparing an EIS. The FONSI will include these mitigation measures, which must be implemented simultaneously with the project/program action (see Sections 5(d)(i)-(iii)).

(e) Mitigation includes: (1) Avoiding the impact altogether by not taking a certain action or parts of an action. (2) Minimizing impacts by limiting the degree or magnitude of the action and its implementation. (3) Rectifying the impact by repairing, rehabilitating, or restoring the affected environment. (4) Reducing or eliminating the impact over time by preservation and maintenance operation during the life of the action. (5) Compensating for the impact by replacing or providing substitute resources or environments.

7. Subsequent Analyses

(a) Tiering and Programmatic Review

(1) A programmatic review may assist decision-makers and the public in understanding the environmental impact from proposed broad federal actions and activities. A programmatic EIS or EA may be prepared to cover: (i) A broad group of related actions; or (ii) A program, policy, plan, system, or national level proposal that may later lead to individual actions, requiring subsequent NEPA analysis.

(2) A programmatic document is useful in analyzing the cumulative impacts of a group of related actions and when the proposed actions are adequately analyzed can serve as the NEPA review for those actions. Programmatic documents may also be useful in providing the basis for subsequent project-level specific environmental review. A programmatic EIS or EA may contain a broader, less specific, analysis than is done for a specific proposed project. If a programmatic EIS or EA is prepared, DTRA/SCC–WMD will determine whether project-specific EISs or EAs are needed for individual actions. Broad Federal actions analyzed in a programmatic EIS or EA may be evaluated geographically, generically, or by stage of technological development.

(3) The use of a programmatic EIS or EA, and subsequent preparation of a project-specific EIS or EA is referred to as "tiering" the environmental review. Tiering can also be used to sequence environmental documents from the early stage of a proposed action (*e.g.,* need for the action and site selection) to a subsequent stage (*e.g.,* proposed construction) to help focus on issues that are ripe for decision and exclude from consideration issues not yet ripe or already decided. When this approach is used, DTRA/SCC–WMD must ensure that the proposed action is not being segmented by describing the independent utility of each stage. Programmatic and tiered EISs and EAs are subject to the same preparation and processing requirements as other EISs and EAs.

(4) When a programmatic EIS or EA has been prepared, any subsequent EIS or EA for proposed projects within the scope of the programmatic document only needs to incorporate it by reference by summarizing the issues discussed in the programmatic document, providing access to the programmatic EIS or EA, and concentrating the subsequent project-specific EIS or EA on site-specific impacts not covered by the programmatic document. The project-specific document must state how to obtain a copy of the earlier programmatic document (*i.e.,* a Web page or contact person/office).

(b) Supplemental EAs/EISs

(1) Project/Program Managers must prepare a supplemental EA, draft EIS, or final EIS if either of the following occurs: (i) There are substantial changes to the proposed action that are relevant to environmental concerns; or (ii) There are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts.

(2) Significant information is information that paints a dramatically different picture of impacts compared to the description of impacts in the EA or EIS. DTRA/SCC–WMD may also prepare supplements when the purposes of NEPA will be furthered by doing so.

(3) Supplemental documents must be prepared following the same general process as the original EA or EIS addressing the new circumstances, information, or actions and incorporating by reference and summary the original EA or EIS. No new scoping is required for a supplemental EIS, but may be conducted at the discretion of the Project/Program Manager or the Director, J4E.

(4) When a supplemental EA or EIS is completed, a new FONSI or ROD must be issued and made available to the public.

(c) Adoption of EAs/EISs

(1) DTRA/SCC–WMD may adopt in whole or in part, another Federal agency's draft or final EA, the EA portion of another agency's EA/FONSI, or EIS in accordance with 40 CFR 1506.3 and CEQ Guidance, "Improving the Process for Preparing Efficient and Timely Environmental Reviews under the National Environmental Policy Act," March 6, 2012, where DTRA/SCC–WMD's proposed action is substantially the same as the action described in the existing EA or EIS. When another agency's NEPA document does not adequately address DTRA/SCC–WMD's proposed action or meet the applicable standards in the CEQ Regulations and these implementing procedures, then DTRA/SCC–WMD cannot adopt the EA or EIS and should consider which portions of that EA or EIS can be incorporated by reference.

(2) The Project/Program Manager and J4E will independently review the EA or EIS and determine whether it is current, satisfies the requirements of NEPA, and covers the proposed action. In adopting all or part of another agency's NEPA document, DTRA/SCC–WMD takes full responsibility for the scope and content that addresses the relevant DTRA/SCC–WMD action(s).

(3) If the actions covered by the original NEPA analysis and the DTRA/SCC–WMD proposed action are substantially the same, DTRA/SCC–WMD may reissue the EA or EIS as a final document and prepare its own FONSI or ROD. The EA or EIS will be recirculated and a public comment period will be provided per Section 5(e) above. When DTRA/SCC–WMD adopts an EA or EIS where it has acted as a cooperating agency and its comments and suggestions have been satisfied by the lead agency in the original document, then coordination with the public is not required.

8. Actions on Host Installations/Actions Abroad

(a) Actions on Host Installations

DTRA/SCC–WMD must comply with the host installation NEPA implementing regulations, procedures, and guidance in addition to those set forth in this guide, and all environmental compliance actions must be coordinated with the appropriate host installation point of contact. Equivalent host installation documentation may be used to satisfy DTRA/SCC–WMD documentation requirements when signed and approved by DTRA/SCC–WMD and maintained in its administrative record.

(b) Actions Occurring Abroad

(1) Executive Order 12114 is based on the authority vested in the President by the Constitution and the laws of the United States. The objective of the Executive Order is to further foreign policy and national security interests while at the same time taking into consideration important environmental concerns. DTRA/SCC–WMD acts with care in the global commons because the stewardship of these areas is shared by all the nations of the world. DTRA/SCC–WMD will take account of environmental considerations when it acts in the global commons in accordance with these procedures.

(2) DTRA/SCC–WMD also acts with care within the jurisdiction of a foreign nation. Treaty obligations and the sovereignty of other nations must be respected, and restraint must be exercised in applying United States laws within foreign nations unless the Congress has expressly provided otherwise. DTRA/SCC–WMD will take account of environmental considerations in accordance with these procedures when it acts in a foreign nation.

(3) Foreign policy considerations require coordination with the Department of State on communications with foreign governments concerning environmental agreements and other formal arrangements with foreign governments concerning environmental matters. Informal working-level communications and arrangements are not included in this coordination requirement. Consultation with the Department of State also is required in connection with the utilization of additional exemptions from these procedures.

(4) Executive Order 12114, implemented by these procedures, prescribes the exclusive and complete procedural measures and other actions to be taken by DTRA/SCC–WMD to further the purpose of the National Environmental Policy Act with respect to the environment outside the United States. As such, actions with potential for significant environmental impact occurring abroad or in the global commons outside the jurisdiction of any nation (*e.g.,* the ocean or Antarctica) are subject to the environmental analysis procedures set forth in this Guide with the exception of hosting public meetings. Project/Program Managers may choose to host public meetings in consideration of the following factors: (i) Foreign relations sensitivities. (ii) Whether the hearings would be an infringement or create the appearance of infringement on the sovereign responsibilities of another government. (iii) Requirements of domestic and foreign governmental confidentiality. (iv) Requirements of national security. (v) Whether meaningful information could be obtained through hearings; (vi) Time considerations. (vii) Requirements for commercial confidentiality.

(5) Consideration will be given to whether any foreign government should be informed of the availability of environmental documents. Communications with foreign governments concerning environmental agreements and other formal arrangements with foreign governments concerning environmental matters must be coordinated by the J0XG with the Department of State through the Assistant Secretary of Defense (International Security Affairs).

9. Classified Actions

(a) Classification of an action for national security does not relieve DTRA/SCC–WMD from the requirements of NEPA. DTRA/SCC–WMD will prepare, safeguard, and disseminate NEPA documents in accordance with DoD requirements for classified information.

(b) Classified information in NEPA documents will be written in a separate appendix from unclassified information so that the unclassified portions of the documents can be made available to the public.

(c) When classified information is an integral part of the analysis so that a meaningful unclassified NEPA analysis cannot be produced, the Project/Program Manager in coordination with the J4E will form a team to review the classified NEPA analysis. This team will include environmental professionals and subject matter experts who will ensure the consideration of environmental effects is consistent with the intent of NEPA, including public participation requirements for unclassified portions.

10. Administrative Record

(a) The J4E will maintain an administrative record for each environmental analysis performed and an administrative record to support these implementing procedures.

(b) The administrative record for a proposed action must be retained for 7 years after completing the action, unless the action involves controversy concerning environmental effects or is of a nature that warrants keeping it longer as determined by the J4E.

(c) The administrative records maintained will include, but are not limited to: (1) All supporting documentation used to generate DTRA/SCC–WMD's NEPA implementing procedures and CATEXs. (2) All supporting documentation and information used to make a decision for Agency actions with potential for significant environmental impact. (3) Maps and other documents relevant to developing an EA or EIS. (4) Formal communication by a consulting, coordinating, or cooperating agency. (5) Studies and inventories of affected environmental resources. (6) Correspondence with regulatory agencies, private citizens, tribes, State or local governments, and other individuals and agencies contacted during public involvement.

11. Glossary

(a) Abbreviations and Acronyms

CATEX	Categorical Exclusion
CEQ	Council on Environmental Quality
DoD	Department of Defense
DTRA/SCC–WMD	Defense Threat Reduction Agency and United States Strategic Command Center for Combating Weapons of Mass Destruction
EA	Environmental Assessment
EIS	Environmental Impact Statement
EPA	Environmental Protection Agency
ESOH	Environment, Safety, and Occupational Health
FIRS	Federal Information Relay Service
FONSI	Finding of No Significant Impact
FR	Federal Register
JO	Director, DTRA/SCC–WMD
JOGC	Office of the General Counsel
JOXG	Governmental and Public Affairs Office
J4/8	Acquisition, Finance, and Logistics Directorate
J4E	Environment, Safety, and Occupational Health Department
JDIR	Joint Director
NEPA	National Environmental Policy Act
NOA	Notice of Availability
NOI	Notice of Intent
REC	Record of Environmental Consideration
ROD	Record of Decision
TDD	telecommunication devices for the deaf

(b) Definitions

Unless otherwise noted, these terms and their definitions are for the purpose of this NEPA Procedures Guide. The definitions in 40 CFR parts 1500–1508 control in the event of any inconsistency or difference.

CATEX. A CATEX is defined at 40 CFR 1508.4 as a category of actions which do not individually or cumulatively have a significant effect on the human environment and which have been found to have no such effect in Federal agency NEPA implementing procedures and, therefore, neither an EA nor an EIS is required. This Guide provides for extraordinary circumstances in which an action that is normally categorically excluded may have a significant effect and therefore merit further analysis in an EA or EIS.

Cooperating agency. A cooperating agency, defined at 40 CFR 1508.5, is any Federal agency or State, tribal, or local governmental entity which has jurisdiction by law or special expertise with respect to any environmental impact involved in a proposed action or a reasonable alternative. The selection and responsibilities of a cooperating agency are described at 40 CFR 1501.6.

EA. An EA, defined at 40 CFR 1508.9, is a concise public document for which a Federal agency is responsible that serves to: (1) Briefly provide sufficient evidence and analysis for determining whether to prepare an EIS or a FONSI; and (2) aid an agency's compliance with NEPA when no environmental impact is necessary. An EA includes an evaluation of whether a project's potential environmental impacts may be significant. Includes an evaluation of the No Action Alternative and other alternatives to the proposed project, and results in either a FONSI or an NOI.

EIS. An EIS, defined at 40 CFR 1508.11, is a detailed written evaluation of the potential environmental impacts and socioeconomic impacts of a proposed action (project), including an evaluation of the No Action Alternative and other alternatives to the proposed project. The EIS identifies mitigation measures needed to address adverse environmental impacts.

Environmental planning. The process of identifying and considering environmental factors that impact on, or are impacted by, planned DoD activities and operations.

FONSI. A FONSI, defined at 40 CFR 1508.13, is a document briefly presenting the reasons why the proposed action, based on the EA findings, will not have a significant effect on the human environment and therefore an EIS is not required.

Impact. Any change to the environment wholly or partially resulting from an organization's activities, products, or services. Impact is synonymous with effect as defined at 40 CFR 1508.7 and 8.

NEPA. The National Environmental Policy Act (NEPA) [42 U.S.C. 4321 *et seq.*] establishes national environmental policy and goals for the protection, maintenance, and enhancement of the environment and provides a process for implementing these goals within Federal agencies. NEPA also established the Council on Environmental Quality.

NOA. A notice of availability is a document notifying the public and other government agencies that an EA or an EIS is available for review.

NOI. A notice of intent, as defined at 40 CFR 1508.22, is a notice that an EIS will be prepared and considered. This notice includes a description of the proposed action and possible alternatives, a description of the agency's proposed scoping process, and the name and address of an agency representative who can answer questions about the proposed action and the EIS.

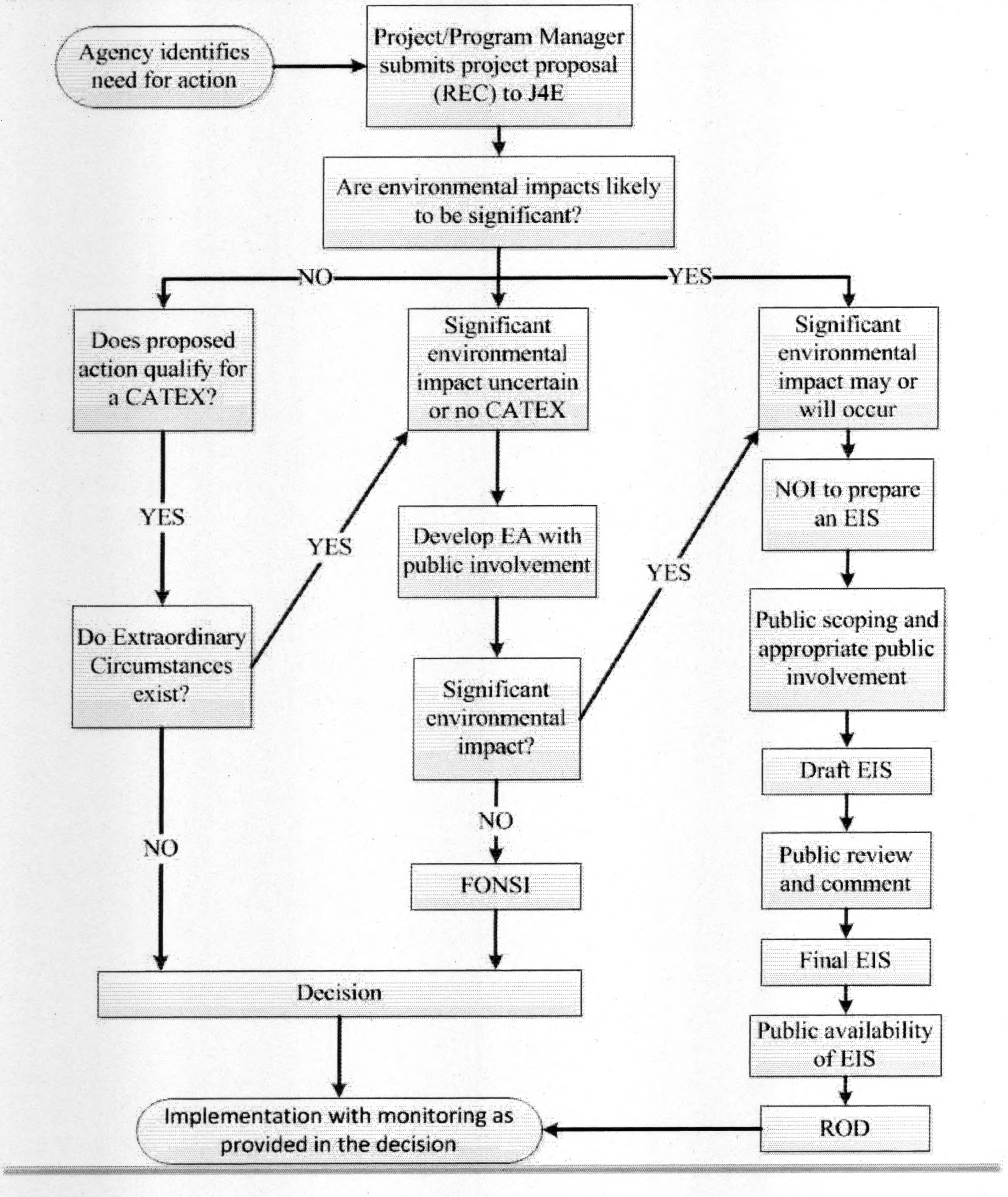
Proponent. The organization that exercises primary management responsibility for a proposed action or activity.

REC. Document stating that the proposed action (project) does not require further NEPA documentation.

Appendix A: The NEPA Process

BILLING CODE 5001–06–P

The NEPA Process


Agency identifies need for action
Project/Program Manager submits project proposal (REC) to J4E
Are environmental impacts likely to be significant?
NO
YES
Does proposed action qualify for a CATEX?
YES
Do Extraordinary Circumstances exist?
YES
NO
Significant environmental impact uncertain or no CATEX
Develop EA with public involvement
Significant environmental impact?
YES
NO
FONSI
Significant environmental impact may or will occur
NOI to prepare an EIS
Public scoping and appropriate public involvement
Draft EIS
Public review and comment
Final EIS
Public availability of EIS
ROD
Decision
Implementation with monitoring as provided in the decision

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Appendix B: Categorical Exclusions (CATEXS)

This Appendix includes categorical exclusions (CATEXs) and extraordinary circumstances for DTRA/SCC–WMD activities.

Actions categorically excluded in the absence of extraordinary circumstances are:

1. Normal personnel, fiscal or budgeting, and administrative activities and decisions, including those involving military and civilian personnel (for example, recruiting, processing, data collection, conducting surveys, payroll, and record keeping).

2. Preparing, revising, or adopting regulations, instructions, directives, or guidance documents, including those that implement without substantial change to the

regulations, instructions, directives, or guidance documents from higher headquarters or other Federal agencies.

3. Decreases, increases, relocation, and realignment of personnel into existing Federally-owned or commercially-leased space that does not involve a substantial change affecting the supporting infrastructure or use of space (*e.g.,* no increase in traffic beyond the capacity of the supporting network to accommodate such an increase).

4. Routine procurement of goods and services conducted in accordance with applicable procurement regulations and green purchasing requirements including office supplies, equipment, mobile assets, and utility services for routine administration, operation, and maintenance.

5. Administrative study efforts involving no commitment of resources other than personnel and funding allocations. If any of these study efforts result in proposals for further action, those proposals must be considered separately by an appropriate CATEX or NEPA analysis. Examples include, but are not limited to: Studies and surveys conducted to further administrative, personnel-related, architectural, engineering, safety, security, siting, and facility audit activities.

6. Studies, monitoring, data and sample collection, and information gathering that involve no permanent physical change to the environment. If any of these activities result in proposals for further action, those proposals must be considered by an appropriate CATEX or NEPA analysis. Examples include, but are not limited to: Surveys for threatened and endangered species, wildlife and wildlife habitat, historic properties, and archeological sites; wetland delineations; minimal water, air, waste; material and soil sampling (*e.g.,* grab samples). Environmental Baseline Surveys or Environmental Condition of Property Surveys. Topographical surveying and mapping that does not require cutting and/or removal of trees.

7. Sampling, borehole drilling, well drilling and installation, analytical testing, site preparation, and minimally intrusive physical testing. These activities could involve minor clearing, grubbing, or movement of heavy equipment such as drill rigs. If any of these actions result in proposals for further actions, those proposals must be considered by an appropriate CATEX or NEPA analysis. Examples include, but are not limited to: Sampling for asbestos-containing materials, polychlorinated biphenyls, and lead-based paint. Topographical surveys and surveys for unexploded ordnance. Minimally-intrusive (no more than 25 square feet of disturbed surface area) geological, geophysical surveys, geo-technical activities, and seismic studies. Minimally-intrusive sampling to determine if hazardous wastes, contaminants, pollutants, or special hazards are present. Ground water monitoring wells, subsurface soil sampling, and soil borings.

8. Immediate responses to the release or discharge of oil or hazardous materials in accordance with an approved Spill Prevention, Control and Countermeasure Plan or Spill Contingency Plan, or that is otherwise consistent with the requirements of the EPA National Contingency Plan.

9. Temporary use of transportable power generators or operational support equipment when located in a previously disturbed area and when operated in compliance with applicable regulatory requirements.

10. Routine movement, handling, use, and distribution of materials, including hazardous materials or wastes that are moved, handled, or distributed in accordance with applicable regulations, such as Resource Conservation and Recovery Act, National Oil and Hazardous Substance Pollution Contingency Plan, Occupational Safety and Health Act, and Hazardous Materials Transportation Act.

11. Routine movement of mobile test assets (such as instrument trailers, cameras, portable antennas, etc.) for routine test and evaluation, for repair, overhaul, or maintenance where no new support facilities are required.

12. Activities and operations to be conducted in an existing non-historic structure which are within the scope of and are compatible with the present functional use of the building, will not result in a substantial increase in waste discharged to the environment, will not result in substantially different waste discharges from current or previous activities, and emissions will remain within established permit limits, if any.

13. Acquisition, installation, modification, routine repair and replacement, and operation of utility (*e.g.,* water, sewer, and electrical) and communication systems, mobile antennas, data processing cable, and similar electronic equipment that use existing rights-of-way, easements, distribution systems, facilities, or previously disturbed land.

14. Acquisition, installation, or minor relocation, operation and maintenance or evaluation of physical security devices or controls to protect human or animal life and to enhance the physical security of existing critical assets in compliance with applicable Federal, tribal, state, and local requirements to protect the environment. Examples include, but are not limited to: Motion detection systems. Lighting. Remote video surveillance systems. Access controls. Physical barriers, fences, grating, on or adjacent to existing facilities.

15. Installation and maintenance of archaeological, historical, and endangered or threatened species avoidance markers, fencing, and signs.

16. Road or trail construction and repair on existing rights-of-ways or in previously disturbed areas which do not result in a change in functional use. Runoff, erosion, and sedimentation controlled through implementation of best management practices.

17. Routine repair and maintenance of buildings, grounds, and other facilities and equipment which do not result in a change in functional use or a significant impact on a historically significant element or setting. Examples include, but are not limited to: Repair of roofs, doors, windows, or fixtures, localized pest management, and minor erosion control measures.

18. New construction or equipment installation or alterations (interior and exterior) to or construction of an addition to an existing structure that is similar to existing land use if the area to be disturbed has no more than five cumulative acres of new surface disturbance.

19. Demolition of non-historic buildings, structures, or other improvements and repairs that result in disposal of debris therefrom, or removal of a part thereof for disposal, in accordance with applicable regulations, including those regulations applying to removal of asbestos containing materials, polychlorinated biphenyls, lead-based paint, and other special hazard items.

20. Research, testing, and operations conducted at existing facilities (including contractor-operated laboratories and plants) and in compliance with all applicable safety, environmental, and natural conservation laws (because of these controls, these types of activities have little potential for significant environmental impacts). Examples include, but are not limited to: Nuclear weapons effects simulators, weapons performance measurement, wind tunnels, high energy lasers, remote sensing instruments, vacuum chambers, high altitude simulator facilities, and propellant testing facilities.

21. Routine installation and use of radars, cameras, communications equipment, and other essentially similar facilities and equipment within a launch facility, mobile platform, military installation, training area, or previously disturbed area that conform to current American National Standards Institute/Institute of Electrical and Electronics Engineers guidelines, Federal Communications Commission Radio Frequency Exposure Limits 1.1310, and Electric and Magnetic Fields Exposure Directive 99/519/EC for maximum permissible exposure to electromagnetic fields.

22. Routine law and order activities performed by military personnel, military police, or other security personnel, including physical plant protection and security.

Extraordinary circumstances that preclude the use of a CATEX are:

1. A reasonable likelihood of significant impact on public health or safety.

2. A reasonable likelihood of significant environmental effects (direct, indirect, and cumulative).

3. A reasonable likelihood of involving effects on the environment that involve risks that are highly uncertain, unique, or are scientifically controversial.

4. A reasonable likelihood of violating any Executive Order, or Federal, state, or local law or requirements imposed for the protection of the environment.

5. A reasonable likelihood of adversely affecting "environmentally sensitive" resources, unless the impact has been resolved through another environmental process (*e.g.,* Coastal Zone Management Act, National Historic Preservation Act, Clean Water Act, etc.) a CATEX cannot be used. Environmentally sensitive resources include: a. Proposed federally listed, threatened, or endangered species or their designated critical habitats. b. Properties listed or

eligible for listing on the National Register of Historic Places. c. Areas having special designation or recognition such as prime or unique agricultural lands; coastal zones; designated wilderness or wilderness study areas; wild and scenic rivers; National Historic Landmarks (designated by the Secretary of the Interior); floodplains; wetlands; sole source aquifers (potential sources of drinking water); National Wildlife Refuges; National Parks; areas of critical environmental concern; or other areas of high environmental sensitivity. d. Cultural, scientific or historic resources.

6. A reasonable likelihood of dividing or disrupting an established community or planned development, or is inconsistent with existing community goals or plans.

7. A reasonable likelihood of causing an increase in surface transportation congestion that will decrease the level of service below acceptable levels.

8. A reasonable likelihood of adversely impacting air quality or violating federal, state, local or tribal air quality standards under the Clean Air Act Amendments of 1990.

9. A reasonable likelihood of adversely impacting water quality, sole source aquifers, public water supply systems or state, local, or tribal water quality standards established under the Clean Water Act and the Safe Drinking Water Act.

10. A reasonable likelihood of effects on the quality of the environment that are highly controversial on environmental grounds. The term "controversial" means a substantial dispute exists as to the size, nature, or effect of the proposed action rather than to the existence of opposition to a proposed action, the effect of which is relatively undisputed.

11. A reasonable likelihood of a disproportionately high and adverse effect on low income or minority populations (see Executive Order 12898).

12. Limit access to and ceremonial use of Indian sacred sites on Federal lands by Indian religious practitioners or significantly adversely affect the physical integrity of such sacred sites (see Executive Order 13007).

13. Contribute to the introduction, continued existence, or spread of noxious weeds or non-native invasive species known to occur in the area or actions that may promote the introduction, growth, or expansion of the range of such species (Federal Noxious Weed Control Act and Executive Order 13112).

14. A greater scope or size than is normal for this category of action.

15. A reasonable likelihood of degrading already existing poor environmental conditions. Also, initiation of a degrading influence, activity, or effect in areas not already significantly modified from their natural condition.

16. A precedent (or makes decisions in principle) for future or subsequent actions that have a reasonable likelihood of having a future significant effect.

17. Introduction or employment of unproven technology.

18. A reasonable likelihood of (i) releases of petroleum, oils, and lubricants (except from a properly functioning engine or vehicle) or reportable releases of hazardous or toxic substances as specified in 40 CFR part 302, Designation, Reportable Quantities, and Notification); (ii) application of pesticides and herbicides; (iii) or where the proposed action results in the requirement to develop or amend a Spill Prevention, Control, or Countermeasures Plan.

Appendix C: Record of Environmental Consideration (REC)

DEFENSE THREAT REDUCTION AGENCY/ UNITED STATES STRATEGIC COMMAND CENTER FOR COMBATING WEAPONS OF MASS DESTRUCTION (DTRA/SCC–WMD)

RECORD OF ENVIRONMENTAL CONSIDERATION

DATE OF REQUEST: ____________________
PROJECT/PROGRAM MANAGER: ________
PHONE NUMBER: ____________________
EMAIL: ____________________________
ORGANIZATION ADDRESS:
____
____
____
PROJECT TITLE: ____________________
PROPOSED PROJECT START DATE: _____
END DATE: _________________________
A. PURPOSE AND NEED FOR ACTION:

B. PROJECT SPECIFIC DETAILS (PROPOSED LOCATION, etc.):

C: LIST OF PREVIOUS NEPA DOCUMENTATION (EA/EIS) FOR THIS OR SIMILAR ACTIVITY

PRINT NAME ________________________
SIGNED ____________________________
[Name of Project/Program Manager]
DATE ______________________________
J4E ENVIRONMENTAL REVIEW ACTION
NOT SUBJECT TO NEPA REQUIREMENTS
PROPOSED ACTION QUALIFIES FOR CATEGORICAL EXCLUSION (CATEX) # _______
PROPOSED ACTION DOES NOT INVOLVE EXTRAORDINARY CIRCUMSTANCES THAT MERIT REVIEW IN AN EA OR EIS (IDENTIFY ANY ENVIRONMENTAL PROCESS THAT HAS RESOLVED AN IMPACT ARISING FROM AN EXTRAORDINARY CIRCUMSTANCE) ________________________
PROPOSED ACTION IS COVERED UNDER EXISTING ENVIRONMENTAL DOCUMENTATION (SPECIFY DOCUMENT AND SECTIONS) ________________________
FURTHER ANALYSIS IS REQUIRED _____
REMARKS: __________________________
PRINT NAME ________________________
SIGNED ____________________________
DATE ______________________________
Director, Environment, Safety, and Occupational Health Department

DTRA/SCC–WMD
8725 John J. Kingman Rd.
Ft. Belvoir, VA 22060

Appendix D: Notice of Intent (NOI)

DEFENSE THREAT REDUCTION AGENCY/ UNITED STATES STRATEGIC COMMAND CENTER FOR COMBATING WEAPONS OF MASS DESTRUCTION (DTRA/SCC–WMD)

[Name of Office; Location; Short Title or Subject of the Notice]

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: [Briefly describe the nature and scope of the proposed action. Do not put legal citations or background information in the SUMMARY section; these belong in the SUPPLEMENTARY INFORMATION section.]

DATES: Comments concerning the scope of the analysis must be received by [insert date 30 days from date of publication in the **Federal Register**].

The draft environmental impact statement is expected [insert estimated month and year] and the final environmental impact statement is expected [insert estimated month and year.]

ADDRESSES: Send written comments to [insert address]. Comments may also be sent via email to [insert email address], or via facsimile to [insert fax number]. [In this section, you also may put additional addresses, locations of meetings, etc. Do not put more than four addresses in this section. If there are more than four pertinent addresses, create a heading for them under the SUPPLEMENTARY INFORMATION section of the notice.]

It is important that reviewers provide their comments at such times and in such a way that they are useful to the Agency's preparation of the EIS. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered.

FOR FURTHER INFORMATION CONTACT: [insert name(s) and contact information you wish to use, such as telephone number and email address].

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m. Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

[Describe why DTRA/SCC–WMD is proposing the action: Why here? Why now?]

Proposed Action

[Describe the proposed action. Consider who, what, how, where, and when.]

Possible Alternatives

[Include only if any have been identified (delete heading if not used or request input on any alternatives considered reasonable—including technically and economically feasible—that will meet the purpose and need).]

Lead and Cooperating Agencies

[Include only if there are other agencies to list as joint lead agencies and/or cooperating agencies (delete heading if not used).]

Responsible Official

[Provide the title and address of the official(s) responsible for the proposed action. Use of the responsible official's name is optional.]

Nature of Decision To Be Made

[Describe the framework or scope of the decision(s) to be made by the responsible official(s).]

Preliminary Issues

[Include only if any have been identified (delete heading if not used). To the extent practicable, resolve internal issues before proposing the action.]

Permits or Licenses Required

[Include only if any have been identified (delete heading if not used).]

Addresses

[Include only if all addresses could not be included in the SUMMARY (delete heading if not used).]

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. [Describe any other public comment opportunities, including whether, when, and where any scoping meetings will be held. Describe any additional information related to the scoping process and nature of comments being sought.]

[Name]

Date

Chief, Governmental and Public Affairs Office

DTRA/SCC–WMD

Appendix E: Notice of Availability (NOA)

DEFENSE THREAT REDUCTION AGENCY/UNITED STATES STRATEGIC COMMAND CENTER FOR COMBATING WEAPONS OF MASS DESTRUCTION (DTRA/SCC–WMD)

AGENCY: [Office name], DTRA/SCC–WMD, Department of Defense

ACTION: Notice of Availability of the [Draft EA, Final EA and FONSI, Draft EIS, Final EIS, or ROD]

SUMMARY: DTRA/SCC–WMD announces the availability of the [insert type of NEPA document] for a proposed project in [insert location].

DATES: [As applicable, list dates of public scoping meetings, deadlines for comments, etc.]

ADDRESSES: [As applicable, list addresses for public scoping meetings, availability of the document, etc.] The [insert Draft EIS, Final EIS, ROD as appropriate] is also available at [insert project Web site.]

FOR FURTHER INFORMATION CONTACT: [insert name(s) and contact information you wish to use, such as telephone number and email address.]

SUPPLEMENTARY INFORMATION: Effective [Date], the DTRA/SCC–WMD assumed environmental responsibilities for this project. DTRA/SCC–WMD as the agency responsible for the National Environmental Policy Act (NEPA) review has, in cooperation with [insert cooperating agencies], prepared a [insert type of NEPA document] on a proposal for [insert brief description of action] in [location]. [Provide additional details regarding the proposed action, description of the proposed alternatives, length of project, and any anticipated federal approvals, such as permits].

Issued on: [Date signed]

[Name]

Chief, Governmental and Public Affairs Office

DTRA/SCC–WMD

Appendix F: Record of Decision (ROD)

RECORD OF DECISION

[Project Name]

DEFENSE THREAT REDUCTION AGENCY/UNITED STATES STRATEGIC COMMAND CENTER FOR COMBATING WEAPONS OF MASS DESTRUCTION (DTRA/SCC–WMD)

[Project Location]

[County, State]

Decision

Based on my review of the Environmental Impact Statement (EIS), I have decided to implement Alternative [X], which [insert description of selected alternative. Include any permits, licenses, grants, or authorizations needed to implement the decision. Also include any mitigation and monitoring actions related to the decision.]

Background

[Provide a brief description of the purpose and need for action.]

Decision Rationale

[Describe the reasons for the decision. Specifically, discuss the following:

How the selected action/alternative best meets the purpose and need and why other alternatives were not selected.

How significant issues and environmental impacts were considered and taken into account.

Any factors other than environmental effects considered in making the decision.

Discuss how the above factors influenced the decision (are some more important than others?)

State whether all practical means to avoid or minimize environmental harm from the selected alternative have been adopted and if not, why not.]

The [Project Name] EIS documents the analysis and conclusions upon which this decision is based.

Public Involvement

A notice of intent to prepare an EIS was published in the **Federal Register** on [date] ([Cite **Federal Register** volume and beginning page number (*i.e.* 73 FR 43084]). People were invited to review and comment on the proposal through [insert public notice methods and dates such as mailings, news releases, phone calls, etc.]. The EIS lists agencies, organizations, and people who received copies on page [X].

The following issues were identified from scoping comments and were used to determine the scope of the analysis. [Briefly describe the significant issues used in the analysis]. A full description of issues significant to the proposed action appears in the EIS on page [X].

A draft EIS was published for review and comment on [date of publication of EPA's notice of availability in the **Federal Register**].

Alternatives Considered

In addition to the selected alternative, I considered [X] other alternatives, which are discussed below. A more detailed comparison of these alternatives can be found in the EIS on pages [X–X].

Alternative 1—[insert a brief description of the alternative; identify which is considered to be environmentally-preferable.]

Alternative 2—[insert a brief description of the alternative]

[Repeat for each alternative.]

Mitigation

[State (a) which mitigation measures have been adopted; (b) whether all practicable means to avoid or minimize have been adopted, and if not why they were not; and (c) whether monitoring and enforcement programs are adopted, and if so summarize them.]

Implementation Date

[Describe the expected date(s) of implementation].

Contact

For additional information concerning this decision, contact: [contact name, title, office, mailing address, phone number, and email]

Concurrence:

[Name]
Project/Program Manager

Date

Director, J4E

Date

Approval:

Director, DTRA/SCC–WMD

Date

[FR Doc. 2016–21294 Filed 9–2–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0096]

Agency Information Collection Activities; Comment Request; Student Assistance General Provisions—Subpart K—Cash Management

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before November 7, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0096. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–347, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Student Assistance General Provisions—Subpart K—Cash Management.

OMB Control Number: 1845–0038.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Individuals or Households; Private Sector.

Total Estimated Number of Annual Responses: 26,266,031.

Total Estimated Number of Annual Burden Hours: 1,194,318.

Abstract: This request is for a revision to the current information collection 1845–0038 that is expiring. This collection pertains to the recordkeeping requirements contained in the regulations related to the administration of the Subpart K—Cash Management section of the Student Assistance General Provisions. The regulatory language has not changed. These program regulations are designed to provide benefits to title IV, HEA applicants, and protect the taxpayers' interest. The information collection requirements in these regulations are necessary to provide students with required information about their eligibility to receive funding under the federal student financial aid programs and to prevent fraud and abuse of program funds by allowing students to reduce or reject aid being offered as well as being made aware of when such funding can be expected to be available.

Dated: August 31, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–21291 Filed 9–2–16; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Sunshine Act Meeting Notice

AGENCY: U.S. Election Assistance Commission.

ACTION: Notice of Public Meeting Agenda.

DATE & TIME: Thursday, September 8, 2016, (1:00–4:00 p.m.—EDT).

PLACE: 1335 East West Highway (First Floor Conference Room) Silver Spring, MD 20910.

AGENDA: Commissioners will meet to announce the winners of a national competition for the top election worker best practices from around the country. Commissioners will hear from state and local election officials and other experts to discuss: (1) Successful practices on election administration and management of the voter registration process; (2) activities regarding National Voter Registration Day; and (3) election system security.

STATUS: This meeting will be open to the public.

PERSON TO CONTACT FOR INFORMATION: Bryan Whitener, Telephone: (301) 563–3961.

Bryan Whitener,

Director of Communications and Clearinghouse, U.S. Election Assistance Commission.

[FR Doc. 2016–21441 Filed 9–1–16; 4:15 pm]

BILLING CODE 6820–KF–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, September 28, 2016, 1:00 p.m.–5:15 p.m.

ADDRESSES: New Mexico Highlands University, Student Union Building, 800 National Avenue, Las Vegas, New Mexico 87701.

FOR FURTHER INFORMATION CONTACT: Menice Santistevan, Northern New Mexico Citizens' Advisory Board (NNMCAB), 94 Cities of Gold Road, Santa Fe, NM 87506. Phone (505) 995–0393; Fax (505) 989–1752 or Email: *Menice.Santistevan@em.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

- Call to Order
- Welcome and Introductions
- Approval of Agenda and Meeting Minutes of July 27, 2016
- Old Business
- New Business
  - ○ Report From Nominating Committee on Election of Officers
  - ○ Election of Chair and Vice Chair for Fiscal Year 2017
  - ○ Report From RADWASTE Summit
  - ○ Report From DOE National Cleanup Workshop
- Update From Co-Deputy Designated Federal Officers
- Presentation: Follow-on Contract Scope

- Presentation: Air Monitoring at Los Alamos National Laboratory
- Presentation: Waste Isolation Pilot Plant (WIPP) Recovery
- Public Comment Period
- Updates From EM Los Alamos Field Office and New Mexico Environment Department
- Wrap-Up Comments From NNMCAB Members
- Adjourn

Public Participation: The EM SSAB, Northern New Mexico, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Menice Santistevan at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Menice Santistevan at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Menice Santistevan at the address or phone number listed above. Minutes and other Board documents are on the Internet at: *http://energy.gov/em/nnmcab/northern-new-mexico-citizens-advisory-board.*

Issued at Washington, DC, on August 30, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–21311 Filed 9–2–16; 8:45 am]

BILLING CODE 6405–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Notice of Re-Opening Request for Information (RFI): Stakeholder Input on Out-Year Marine and Hydrokinetic Program Strategy

AGENCY: Water Power Technologies Office, Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of reopening of public comment period.

SUMMARY: On April 6, 2016, the Water Power Technologies Office within the U.S. Department of Energy (DOE), published a notice in the **Federal Register** announcing a stakeholder meeting to receive comments on its request for information (RFI) to receive input for DOE's Outyear Marine and Hydrokinetic Program Strategy. Based on requests from several stakeholder to extend the RFI comment period, DOE has decided to reopen the RFI comment period.

DATES: DOE will accept comments no later than Friday, September 30, 2016 at 11:59 p.m. ET.

ADDRESSES: Interested persons can submit comments to the email address: *MHKRFI1570@ee.doe.gov.* Please include with the subject line "Comments for RFI1570."

FOR FURTHER INFORMATION CONTACT: Maggie Yancey, Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy, 1000 Independence Ave SW., Washington, DC 20585. Telephone: (202) 586–4536. For email, please include in the subject line "Further Information," and in the body of the email: your name, organization, contact information, and your specific question or inquiry. *MHKRFI1570@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: On April 6, 2016, the Water Power Technologies Office within the DOE published a notice in the **Federal Register**, (81 FR 19963), announcing a stakeholder meeting to receive comments on its request for information (RFI) to receive input for DOE's Outyear Marine and Hydrokinetic Program Strategy. The RFI, numbered RFI 1570, is available on DOE's EERE Exchange Web site at: *https://eere-exchange.energy.gov/and/or* at this link: *http://bit.ly/2bTiyie.* The RFI has not been changed or modified to include new information that DOE is requesting feedback on; DOE is re-opening RFI 1570 to allow an additional opportunity for comments to be submitted.

Issued on August 30, 2016 in Washington, DC.

James M. Ahlgrimm,

Acting Director, Water Power Technologies Office, Office of Energy Efficiency and Renewable Energy.

[FR Doc. 2016–21307 Filed 9–2–16; 8:45 am]

BILLING CODE 6450–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 10487—Sunrise Bank of Arizona, Phoenix, Arizona

NOTICE IS HEREBY GIVEN that the Federal Deposit Insurance Corporation ("FDIC") as Receiver for Sunrise Bank of Arizona, Phoenix, Arizona ("the Receiver") intends to terminate its receivership for said institution. The FDIC was appointed receiver of Sunrise Bank of Arizona on August 23, 2013. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: August 31, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–21324 Filed 9–2–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL TRADE COMMISSION

SES Performance Review Board

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given of the appointment of members to the FTC Performance Review Board.

FOR FURTHER INFORMATION CONTACT: Vicki Barber, Chief Human Capital Officer, 600 Pennsylvania Avenue NW., Washington, DC 20580, (202) 326–2700.

SUPPLEMENTARY INFORMATION: Publication of the Performance Review

Board (PRB) membership is required by 5 U.S.C. 4314 (c)(4). The PRB reviews and evaluates the initial appraisal of a senior executive's performance by the supervisor, and makes recommendations regarding performance ratings, performance awards, and pay-for-performance pay adjustments to the Chairwoman.

The following individuals have been designated to serve on the Commission's Performance Review Board:

David Robbins, Executive Director, Chairman
David Shonka, Acting General Counsel
Deborah Feinstein, Director, Bureau of Competition
Jessica Rich, Director, Bureau of Consumer Protection
Michael Vita, Deputy Director, Bureau of Economics

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–21402 Filed 9–2–16; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–0607; Docket No. CDC–2016–0087]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on The National Violent Death Reporting System (NVDRS) to continue collecting state-based surveillance data on violent deaths that will provide more detailed and timely information.

DATES: Written comments must be received on or before November 7, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0087 by any of the following methods:

Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

The National Violent Death Reporting System (NVDRS), (OMB Control No. 0920–0607, Expiration 10/31/2017)—Revision—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Violence is an important public health problem. In the United States, suicide and homicide are the second and third leading causes of death, respectively, in the 1–34 year old age group. Unfortunately, public health agencies do not know much more about the problem than the numbers and the sex, race, and age of the victims, or information obtainable from the standard death certificate. Death certificates, however, carry no information about key facts necessary for prevention such as the relationship of the victim and suspect and the circumstances of the deaths. Furthermore, death certificates are typically available 20 months after the completion of a single calendar year. Official publications of national violent death rates, *e.g.* those in Morbidity and Mortality Weekly Report, rarely use data that is less than two years old.

Local and Federal criminal justice agencies such as the Federal Bureau of Investigation (FBI) provide slightly more information about homicides, but they do not routinely collect standardized data about suicides, which are in fact much more common than homicides. The FBI's Supplemental Homicide Report (SHRs) does collect basic information about the victim-suspect relationship and circumstances related to the homicide. SHRs, do not link violent deaths that are part of one incident such as homicide-suicides. It also is a voluntary system in which some 10–20 percent of police departments nationwide do not participate. The FBI's National Incident Based Reporting System (NIBRS) provides slightly more information than SHRs, but it covers less of the country than SHRs. NIBRS also only provides data regarding homicides. Also, the Bureau of Justice Statistics Reports do not use data that is less than two years old.

CDC requests OMB approval in order to revise its state-based surveillance system for violent deaths that will provide more detailed and timely information. The surveillance system captures case record information held by medical examiners/coroners, vital statistics (*i.e.*, death certificates), and law enforcement. Data is collected by each state in the system and entered into a web system administered by CDC. Information is collected from these records about the characteristics of the victims and suspects, the circumstances of the deaths, and the weapons involved. States use standardized data elements and software designed by CDC. Ultimately, this information will guide states in designing, targeting, and evaluating programs that reduce multiple forms of violence. Neither victim's families nor suspects are contacted to collect this information; it all comes from existing records and is collected by state health department staff or their subcontractors. The number of hours per death required for the public agencies working with NVDRS states to retrieve and then refile their records is estimated to be 0.5 hours per death. Moving forward, we will no longer include state abstractors' time spent abstracting data in our estimates of public burden for NVDRS because state abstractors are funded by CDC to do this work. This significantly reduces the estimated public burden associated with NVDRS.

The president has submitted plans to fund the expansion of the state-based surveillance system to collect information in all 50 U.S. states, the District of Columbia, and U.S. territories. This revision will allow 10 new state health departments, and 7 territorial governments to be added to the currently funded 39 state health departments (Maine and Vermont are funded as one entity), the health department of the District of Columbia, and 1 territorial government, resulting in a total of 59 states and territories to be included in the state-based surveillance system. Violent deaths include all homicides, suicides, legal interventions, deaths from undetermined causes, and unintentional firearm deaths. The average state will experience approximately 1,000 such deaths each year.

There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours (in hours)
Public Agencies	NVDRS Web System	59	1,000	30/60	29,500

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–21296 Filed 9–2–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–16–16XD]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Practice Patterns Related to Opioid Use during Pregnancy and Lactation—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Over the past decade, the prevalence of maternal opioid use during pregnancy has steadily increased. The use of opioids or other psychoactive substances, either by illicit abuse or by nonmedical abuse of prescription opioids, increases the risks for health and social problems for both mother and infant. For example, maternal substance abuse during pregnancy increases the risk of preterm birth, low birth weight, perinatal death, and neonatal abstinence syndrome (NAS). For many women, and some at-risk women in particular, prenatal visits may be the only time they routinely see a physician. Because obstetrician-gynecologists (OB/GYNs) are the principal health care providers for women, OB/GYNs are well situated to screen for substance use and to treat or encourage cessation of substance use during pregnancy. Thus, it is important to understand current provider knowledge, attitudes, and practices regarding maternal opioid use.

CDC, in collaboration with the American College of Obstetricians and Gynecologists (ACOG), plans to conduct a survey to address this gap in knowledge. Survey respondents will be ACOG Fellows and Junior Fellows who have a current medical license and are in medical practice focused on women's health. ACOG is separated into 11 districts, one of which represents OB/GYN members who are in the U.S. military. The remaining 10 ACOG districts correspond to geographic regions that encompass the entire United States and Canada. Survey invitations will be sent to a quasi-random sample of ACOG members in each district.

CDC and ACOG estimate that 1,500 individuals will be contacted in order to obtain a study target of 600 respondents. The initial invitation will be distributed by email with instructions on completing a web-based version of the questionnaire. Three to four months after the initial invitation, a paper version of the questionnaire will be distributed to individuals who have not completed the online version. The estimated number of respondents for the full web-based or paper questionnaire is 420 and the estimated burden per response is 15 minutes. Approximately 6 weeks after the second recruitment attempt, ACOG will distribute a short version of the questionnaire to any non-responders. The estimated number of responses for the short version of the questionnaire is 180 and the estimated burden per response is 5 minutes. An overall 40% response rate is expected.

The survey will collect information about provider attitudes and beliefs regarding maternal opioid use, their screening and referral practices for pregnant or postpartum patients, barriers to screening and treating pregnant and postpartum patients for opioid use, and resources that are needed to improve treatment and referral. No information will be collected about individual patients. Survey administration and data management will be conducted by ACOG, and participation is voluntary. De-identified response data will be shared with CDC for analysis. Findings will be used to create recommendations for educational programs and patient care. The total estimated annualized burden hours are 120. There are no costs to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
OB/GYNs caring for pregnant women.	Practice Patterns related to Opioid Use during Pregnancy and Lactation—Full survey.	420	1	15/60
	Practice Patterns related to Opioid Use during Pregnancy and Lactation—Short introduction and survey.	180	1	5/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–21273 Filed 9–2–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Ethnic Community Self-Help Program Data Indicators.

OMB No.: 0970–NEW.

Description: The ACF Office of Refugee Resettlement proposes to collect information from Ethnic Community-Based Organizations (ECBOs) awarded federal funds under HHS–2016–ACF–ORR–1129. The information, collected through a questionnaire, is expected to provide information on Program objectives semi-annually in order for program staff to gauge the Program's progress for reporting and evaluation purposes.

Respondents: ECBOs awarded under HHS–2016–ACF–ORR–1129.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ECSH Data Indicators	10	2	1	20

Estimated Total Annual Burden Hours: 20.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn:

Desk Officer for the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.

[FR Doc. 2016–21250 Filed 9–2–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2526]

Determination That AQUAMEPHYTON (Phytonadione) Injectable and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6207, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 012223	AQUAMEPHYTON	Phytonadione	10 milligram (mg)/milliliter (mL); 1 mg/0.5 mL.	Injectable; Injection	Teligent Pharma Inc.
NDA 016087	VALIUM	Diazepam	5 mg/mL	Injectable; Injection	Roche.
NDA 017090	TOFRANIL–PM	Imipramine Pamoate	Equivalent to (EQ) 75 mg HCl; EQ 100 mg HCl; EQ 125 mg HCl; EQ 150 mg HCl.	Capsule; Oral	Mallinckrodt Pharmaceuticals.
NDA 017558	ROBINUL	Glycopyrrolate	0.2 mg/mL	Injectable; Injection	Eurohealth International Sarl.
NDA 017911	CLINORIL	Sulindac	200 mg	Tablet; Oral	Merck.
NDA 017962	PARLODEL	Bromocriptine Mesylate.	EQ 5 mg base	Capsule; Oral	US Pharmaceuticals Holdings I LLC.
NDA 018579	FUROSEMIDE	Furosemide	10 mg/mL	Injectable; Injection	Luitpold Pharmaceuticals, Inc.
NDA 018687	NORMODYNE	Labetalol Hydrochloride.	100 mg; 200 mg; 300 mg; 400 mg.	Tablet; Oral	Schering-Plough Corp.
NDA 018731	BUSPAR	Buspirone Hydrochloride.	5 mg	Tablet; Oral	Bristol-Myers Squibb.
NDA 018776	NORCURON	Vecuronium Bromide	10 mg/vial; 20 mg/vial	Injectable; for Injection.	Organon USA Inc.
NDA 019773	VENTOLIN	Albuterol Sulfate	EQ 0.083% base	Solution; Inhalation	GlaxoSmithKline.
NDA 019810	PRILOSEC	Omeprazole	10 mg; 20 mg; 40 mg	Capsule, Delayed-Release Pellets; Oral.	AstraZeneca Pharmaceuticals LP.
NDA 020059	ADENOSCAN	Adenosine	60 mg/20 mL (3 mg/mL); 90 mg/30 mL (3 mg/mL).	Solution; I.V. Infusion	Astellas Pharma US, Inc.
NDA 020799	FLOXIN OTIC	Ofloxacin	0.3%	Solution/Drops; Otic	Daiichi-Sankyo.
NDA 021045	PLAN B	Levonorgestrel	0.75 mg	Tablet; Oral	Teva Branded Pharm.
NDA 021214	RESCULA	Unoprostone Isopropyl.	0.15%	Solution/Drops; Ophthalmic.	Sucampo Pharmaceuticals, Inc.
NDA 050459	AMOXIL	Amoxicillin	250 mg; 500 mg	Capsule; Oral	GlaxoSmithKline.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 050460	AMOXIL	Amoxicillin	125 mg/5mL; 50 mg/mL; 250 mg/5 mL.	for Suspension; Oral	GlaxoSmithKline.
NDA 050460	LAROTID	Amoxicillin	50 mg/mL	for Suspension; Oral	GlaxoSmithKline.
ANDA 072652	ALBUTEROL SULFATE.	Albuterol Sulfate	EQ 0.083% base	Solution; Inhalation	Mylan Specialty L.P.
ANDA 075117	ORAPRED	Prednisolone Sodium Phosphate.	EQ 15 mg base/5 mL	Solution; Oral	Concordia Pharmaceuticals Inc.
ANDA 075385	BUSPIRONE HYDROCHLORIDE.	Buspirone Hydrochloride.	5 mg; 10 mg; 15 mg	Tablet; Oral	Teva Pharmaceuticals USA, Inc.
ANDA 078665	LEVONORGESTREL	Levonorgestrel	0.75 mg	Tablet; Oral	Watson Labs.
ANDA 087811	PHRENILIN	Acetaminophen; Butalbital.	325 mg; 50 mg	Tablet; Oral	Valeant Pharmaceuticals International Inc.
ANDA 088825	BUTALBITAL, ACETAMINOPHEN AND CAFFEINE.	Acetaminophen; Butalbital; Caffeine.	325 mg; 50 mg; 40 mg.	Capsule; Oral	Gilbert Labs.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21227 Filed 9–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1064]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in the Medical Device Fellowship Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the application for participation in the Medical Device Fellowship Program.

DATES: Submit either electronic or written comments on the collection of information by November 7, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. [FDA–2013–N–1064] for "Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in the Medical Device Fellowship Program."

Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the

Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Application for Participation in the Medical Device Fellowship Program—OMB Control Number 0910–0551—Extension

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of title 5 of the United States Code authorize Federal Agencies to rate applicants for Federal jobs. Collecting applications for the Medical Device Fellowship Program will allow FDA's Center for Devices and Radiological Health (CDRH) to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in CDRH activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with CDRH.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Application Form (FDA 3608)	250	1	250	1	250

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21229 Filed 9–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0380]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 6, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0523. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications—21 CFR Part 3—OMB Control Number 0910–0523—Extension

This regulation relates to Agency management and organization and has two purposes. The first is to implement section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)), as added by the Safe Medical Devices Act of 1990 (Pub. L. 101–629), and amended by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), by specifying how FDA will determine the organizational component within FDA assigned to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of: (1) A drug and a device; (2) a device and a biological product; (3) a biological product and a drug; or (4) a drug, a device, and a biological product.

The second purpose of this regulation is to enhance the efficiency of Agency management and operations by providing procedures for classifying and determining which Agency component is designated to have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute.

The regulation establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to which Agency component should have primary jurisdiction, with an accompanying statement of reasons. The information submitted would be used by FDA as the basis for making the assignment or designation decision. Most information required by the regulation is already required for premarket applications affecting drugs, devices, biological products, and combination products. The respondents will be businesses or other for-profit organizations.

In the **Federal Register** of January 28, 2016 (81 FR4921), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3	84	1	84	24	2,016

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These burden estimates are based on the number of applications FDA received over the past fiscal year.

Dated: August 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21228 Filed 9–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Senior Executive Service Performance Review Board

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In this notice, the Health Resources and Services Administration (HRSA) located within the Department of Health and Human Services (HHS) publishes a list of persons who may be named to serve on the Performance Review Board that oversees the evaluation of performance appraisals for Senior Executive Service members within HRSA.

FOR FURTHER INFORMATION CONTACT: Dora Ober, Executive Resources, Office of Human Resources, 5600 Fishers Lane, Rm 12N06C, Rockville, Maryland 20857, Telephone (301) 443–0759.

SUPPLEMENTARY INFORMATION: Title 5, U.S.C. Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Board Members be published in the **Federal Register**. The following persons may be named to serve on the HRSA Performance Review Board, which will oversee the evaluation of performance appraisals of

Senior Executive Service members for the Fiscal Year 2016 review period:

Leslie Atkinson, Tonya Bowers, Adriane Burton, Tina Cheatham, Laura Cheever, Cheryl Dammons, Elizabeth DeVoss, Diana Espinosa, Catherine Ganey, Alexandra Garcia, Richard Goodman, Heather Hauck, Avril Houston, Laura Kavanagh, Martin Kramer, Sarah Linde, Rimas Liogys, Michael Lu, Dennis Malcomson, James Macrae, Thomas Morris, Kerry Nesseler, William O'Rourke, Luis Padilla, Deborah Parham Hopson, Wendy Ponton, Patricia Stroup.

Dated: August 30, 2016.

James Macrae,

Acting Administrator.

[FR Doc. 2016–21320 Filed 9–2–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Request for Public Comment on Draft Health Center Program Compliance Manual

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for public comment on Draft Health Center Program Compliance Manual.

SUMMARY: HRSA is inviting public comment on the Draft Health Center Program Compliance Manual, hereafter referred to as the Compliance Manual. The purpose of the Compliance Manual is to provide a consolidated web-based resource to assist current and prospective health centers in understanding and demonstrating compliance with requirements of the Health Center Program, a HRSA-administered program authorized under 42 U.S.C. 254b. The Compliance Manual identifies requirements found in the Health Center Program's authorizing legislation and implementing regulations, as well as certain applicable grant regulations. The Compliance Manual also addresses HRSA's approach to determining eligibility for and oversight of the Health Center Program. In addition, the Compliance Manual includes the requirements for obtaining deemed Public Health Service (PHS) employee status under the Federally Supported Health Centers Assistance Acts of 1992 and 1995, for purposes of Federal Tort Claims Act (FTCA) liability protections for the performance of medical, surgical, dental, and related functions within the scope of deemed PHS employment.

DATES: Submit written comments no later than November 22, 2016.

ADDRESSES: Written comments should be submitted through the HRSA/Bureau of Primary Health Care (BPHC) Web site at *http://bphc.hrsa.gov/programrequirements/draftcompliancemanual/index.html.*

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, contact HRSA/BPHC/Office of Policy and Program Development at *HCPComplianceManual@hrsa.gov.*

SUPPLEMENTARY INFORMATION: HRSA provides grants to eligible applicants under section 330(e), (g), (h), and/or (i) of the PHS Act, as amended (42 U.S.C. 254b), to support the delivery of preventive and primary care services to medically underserved communities and vulnerable populations. Nearly 1,400 Health Center Program-funded health centers operate approximately 9,800 service delivery sites that provide care to over 24 million patients in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. HRSA also designates eligible applicants under the Health Center Look-Alike Program (*see* Sections 1861(aa)(4)(B) and 1905(l)(2)(B) of the Social Security Act). Look-Alikes do not receive Health Center Program funding but must meet the Health Center Program statutory and regulatory requirements. Note that for the purposes of the Compliance Manual, the term "health center" refers to entities that receive a federal award under section 330 of the PHS Act, as amended, subrecipients, and organizations designated as look-alikes, unless otherwise stated.

HRSA also makes determinations of deemed PHS employment status for health centers funded under section 330 and their covered individuals for purposes of providing liability protections under the Health Center Federal Tort Claims Act (FTCA) Program. Section 224(g)–(n) of the PHS Act (42 U.S.C. 233(g)–(n)) authorizes the FTCA Program and affords eligibility for FTCA coverage as the exclusive civil remedy for acts or omissions arising from the performance of medical, surgical, dental, or related functions within the scope of such employment by deemed health centers and by any officers, governing board members, employees, and certain individual contractors of these entities. A favorable FTCA deeming determination requires submission of an application by the Health Center Program awardee in the form and manner specified by HRSA.

The Compliance Manual includes sections identifying the requirements found in the Health Center Program's authorizing legislation and program implementing regulations (section 330 of the PHS Act, as amended, 42 CFR part 51c, and 42 CFR part 56); certain applicable HHS grant regulations (45 CFR part 75); and the Health Center FTCA Program's authorizing legislation and implementing regulations (section 224(g)–(n) of the PHS Act, and 42 CFR part 6). Organizations receiving Health Center Program federal awards, including subrecipients, are also subject to all requirements incorporated within documents such as Funding Opportunity Announcements and Notices of Award. The Compliance Manual specifies Health Center Program non-regulatory policy issuances that would be superseded, as well as those that would remain in effect.

The first chapter of the Compliance Manual outlines HRSA's approach to determining organizational eligibility for the Health Center Program, including how to demonstrate non-profit or public agency status. The chapter also describes organizational eligibility requirements that apply only to look-alikes. The second chapter clarifies HRSA/BPHC's oversight process by providing information on how HRSA will address areas of noncompliance and impose enforcement actions, including those for serious violations that may lead to the suspension of grant activities or termination of grant funding by HRSA under 45 CFR part 75.

The Compliance Manual contains 18 chapters on Health Center Program requirements, each of which: (a) Cites the applicable statutory and regulatory authorities; (b) lists statutory and regulatory requirements; (c) describes how health centers would demonstrate compliance to HRSA; and d) includes examples of areas in which health centers have discretion or that may be helpful for health centers to consider when implementing the requirements.

The final chapter specifies the FTCA requirements for obtaining deemed PHS employment status, including how a health center would demonstrate compliance with the FTCA requirements in its annual deeming application. Please note that deemed employment status does not confer FTCA coverage in all cases, as health center providers also must comply with applicable legal eligibility requirements and covered actions must be undertaken within the scope of such deemed PHS employment (for more information, see the *Federal Tort Claims Act Health Center Policy Manual* at *http://*

bphc.hrsa.gov/ftca/healthcenters/ftcahcpolicymanual.html). When FTCA matters become the subject of litigation, the U.S. Department of Justice and the federal courts may assume significant roles in certifying or determining whether or not a given activity falls within the scope of employment, for purposes of FTCA coverage.

Dated: August 30, 2016.

James Macrae,

Acting Administrator.

[FR Doc. 2016–21321 Filed 9–2–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and thediscussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Biology Development and Disease Study Section.

Date: September 28–29, 2016.

Time: 7:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn San Francisco Fisherman's Wharf, 1300 Columbus Avenue, San Francisco, CA 94133.

Contact Person: Aruna K Behera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301–435–6809, *beheraak@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Vector Biology Study Section.

Date: October 5, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Cambria Suites Rockville, 1 Helen Heneghan Way, Rockville, MD 20850.

Contact Person: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301–402–5671, *zhengli@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Alcohol and Motivated Behavior.

Date: October 5–6, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119, *selmanom@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Biophysics of Neural Systems Study Section.

Date: October 5, 2016.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Baltimore, 2 North Charles Street, Baltimore, MD 212013.

Contact Person: Geoffrey G Schofield, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040–A, MSC 7850, Bethesda, MD 20892, 301–435–1235, *geoffreys@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 30, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–21232 Filed 9–2–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; SBIR Direct Phase II, Bioreactors for Reparative Medicine.

Date: September 28, 2016.

Time: 1:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Tony L. Creazzo, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892–7924, 301–435–0725, *creazzotl@mail.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Phase I and Phase II, Bioreactors for Reparative Medicine (SBIR).

Date: September 28, 2016.

Time: 1:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Tony L. Creazzo, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892–7924, 301–435–0725, *creazzotl@mail.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Phase I and Phase II, Bioreactors for Reparative Medicine (STTR).

Date: September 28, 2016.

Time: 12:30 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Tony L. Creazzo, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892–7924, 301–435–0725, *creazzotl@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: August 30, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–21233 Filed 9–2–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Nathan Shock Center Coordinating Center.

Date: October 3, 2016.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Bita Nakhai, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2c212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 30, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–21234 Filed 9–2–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; NIDDK Office of Minority Health Research Coordination (OMHRC) Research Training and Mentor Programs Applications (National Institute of Diabetes and Digestive and Kidney Diseases)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** (Vol. 81, No. 93, page 29877) on May 13, 2016 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Winnie Martinez, Program Officer, OMHRC, NIDDK, NIH, 6707 Democracy Blvd., Room 9215, Bethesda, MD 20892 or call non-toll free number (301) 435–2988 or Email your request including your address to *Winnie.Martinez@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed collection: NIDDK Office of Minority Health Research Coordination (OMHRC) Research Training and Mentor Programs Applications, 0925—New, Existing collection in use without OMB control number, National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of the proposed information collection activity is to assure that prospective trainees to OMHRC Research Training and Mentoring Programs meet basic eligibility requirements; to assess their potential as future scientists; to determine where mutual research interests exist; and to make decisions regarding which applicants will be proposed and approved for traineeship awards. In each case, completing the application is voluntary, but in order to receive due consideration, the prospective trainee must complete all required fields.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2569.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Estimated Number of respondents	Estimated Number of responses annually per respondent	Average burden per response (in hours)	Est. total annual burden hours
Attachment 1: Short-Term Research Experience for Underrepresented Persons (STEP–UP) Application.	Students	2,000	1	45/60	1,500
Attachment 2: STEP–UP Student Feedback Form.	Students	200	1	30/60	100

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Type of respondents	Estimated Number of respondents	Estimated Number of responses annually per respondent	Average burden per response (in hours)	Est. total annual burden hours
Attachment 3: Diversity Summer Research Training Program (DSRTP) Application.	Students	200	1	45/60	150
Attachment 4: DSRTP Feedback Form	Students	40	1	30/60	20
Attachment 5: Network of Minority Research Investigators (NMRI) Enrollment Form.	Researchers	200	1	15/60	50
Attachment 6: NMRI Evaluation Form	Researchers	100	1	15/60	25
Attachment 7: NMRI Survey Form	Researchers	1,000	1	30/60	500
Attachment 8: NMRI Mentor/Mentee/Agreement Forms.	Researchers	100	1	30/60	50
Attachment 9: NIH/NMA Fellows Program on Careers in Academic Medicine Application.	Fellows	200	1	20/60	67
Attachment 10: NIH/NMA Feedback Form	Fellows	40	1	30/60	20
Attachment 11: NIH/NHMA Fellows Program Application Form.	Fellows	200	1	20/60	67
Attachment 12: NIDDK/NHMA Feedback Form	Fellows	40	1	30/60	20
Totals		4,320	4,320		2,569

Dated: August 26, 2016.

Priscilla Logan,

NIDDK Project Clearance Liaison, Office of Management and Policy Analysis, NIDDK, NIH.

[FR Doc. 2016–21329 Filed 9–2–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Fellowship Review.

Date: November 3, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Terrace Conference Room 508/509, Rockville, MD 20892.

Contact Person: Richard A. Rippe, Ph.D., Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Room 2109, Rockville, MD 20852, 301–443–8599, *rippera@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: August 29, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–21235 Filed 9–2–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Lung Cellular, Molecular, and Immunobiology Study Section.

Date: September 28–29, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: George M. Barnas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, 301–435–0696, *barnasg@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR16–044: Image Guided Drug Delivery.

Date: September 30, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Serrano Hotel, 405 Taylor Street, San Francisco, CA 94102.

Contact Person: Mehrdad Mohseni, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7854, Bethesda, MD 20892, 301–435–0484, *mohsenim@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Molecular Neuropharmacology and Signaling Study Section.

Date: October 3–4, 2016.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Lorien Hotel & Spa, 1600 King Street, Alexandria, VA 22314.

Contact Person: Deborah L. Lewis, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4183, MSC 7850, Bethesda, MD 20892, 301–408–9129, *lewisdeb@csr.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Social Psychology, Personality and Interpersonal Processes Study Section.

Date: October 3–4, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Marc Boulay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, (301) 300–6541, *boulaymg@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Bioengineering, Technology and Surgical Sciences.

Date: October 3, 2016.

Time: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854 Bethesda, MD 20892, 301–237–9870, *xuguofen@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 30, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–21243 Filed 9–2–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4277–DR; Docket ID FEMA–2016–0001]

Louisiana; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA–4277–DR), dated August 14, 2016, and related determinations.

DATES: Effective Date: August 16, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Louisiana is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 14, 2016.

Acadia, Ascension, East Feliciana, Iberia, Lafayette, Pointe Coupee, St. Landry, and Vermilion Parishes for Individual Assistance and assistance for debris removal and emergency protective measures (Categories A and B), including direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–21262 Filed 9–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4278–DR; Docket ID FEMA–2016–0001]

Kentucky; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Commonwealth of Kentucky (FEMA–4278–DR), dated August 26, 2016, and related determinations.

EFFECTIVE DATE: August 26, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated August 26, 2016, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

> I have determined that the damage in certain areas of the Commonwealth of Kentucky resulting from severe storms, tornadoes, flooding, landslides, and mudslides during the period of July 2–9, 2016, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the Commonwealth of Kentucky.
>
> In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.
>
> You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the Commonwealth. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.
>
> Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Warren J. Riley, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the Commonwealth of Kentucky have been designated as adversely affected by this major disaster:

Adair, Butler, Caldwell, Calloway, Christian, Clay, Crittenden, Daviess, Edmonson, Hart, Hopkins, Livingston, Lyon, Marshall, Metcalfe, Ohio, Todd, Trigg, Union, and Webster Counties for Public Assistance.

All areas within the Commonwealth of Kentucky are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–21374 Filed 9–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4277–DR; Docket ID FEMA–2016–0001]

Louisiana; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Louisiana (FEMA–4277–DR), dated August 14, 2016, and related determinations.

DATES: Effective on August 14, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated August 14, 2016, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

> I have determined that the damage in certain areas of the State of Louisiana resulting from severe storms and flooding beginning on August 11, 2016, and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of Louisiana.
>
> In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.
>
> You are authorized to provide Individual Assistance and assistance for debris removal and emergency protective measures (Categories A and B) under the Public Assistance program in the designated areas, Hazard Mitigation throughout the State, and any other forms of assistance under the Stafford Act that you deem appropriate subject to completion of Preliminary Damage Assessments (PDAs). Direct Federal assistance is authorized.
>
> Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.
>
> Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Gerard M. Stolar, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Louisiana have been designated as adversely affected by this major disaster:

East Baton Rouge, Livingston, St. Helena, and Tangipahoa Parishes for Individual Assistance.

East Baton Rouge, Livingston, St. Helena, and Tangipahoa Parishes for debris removal and emergency protective measures (Categories A and B), including direct federal assistance, under the Public Assistance program.

All areas within the State of Louisiana are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–21264 Filed 9–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4276–DR; Docket ID FEMA–2016–0001]

Wisconsin; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Wisconsin (FEMA–4276–DR), dated August 9, 2016, and related determinations.

DATES: *Effective Date:* August 9, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated August 9, 2016, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

> I have determined that the damage in certain areas of the State of Wisconsin resulting from severe storms and flooding during the period of July 11–12, 2016, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of Wisconsin.
>
> In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.
>
> You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal

assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Benigno Bern Ruiz, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Wisconsin have been designated as adversely affected by this major disaster:

Ashland, Bayfield, Burnett, Douglas, Florence, Iron, Sawyer, and Washburn Counties and the Bad River Band of the Lake Superior Chippewa Tribe for Public Assistance.

All areas within the State of Wisconsin are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–21259 Filed 9–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4277–DR; Docket ID FEMA–2016–0001]

Louisiana; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA–4277–DR), dated August 14, 2016, and related determinations.

DATES: *Effective Date:* August 16, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Louisiana is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 14, 2016.

Avoyelles, Evangeline, Iberville, Jefferson Davis, St. Martin, St. Tammany, Washington, and West Feliciana Parishes for Individual Assistance.

Avoyelles, Evangeline, Iberville, Jefferson Davis, St. Martin, St. Tammany, Washington, and West Feliciana Parishes for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–21261 Filed 9–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4277–DR; Docket ID FEMA–2016–0001]

Louisiana; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA–4277–DR), dated August 14, 2016, and related determinations.

DATES: *Effective Date:* August 16, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Louisiana is hereby amended to include permanent work under the Public Assistance program for those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 14, 2016.

Acadia, Ascension, East Baton Rouge, East Feliciana, Iberia, Lafayette, Livingston, Pointe Coupee, St. Helena, St. Landry, Tangipahoa, and Vermilion Parishes for Public Assistance [Categories C–G] (already designated for Individual Assistance and assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–21263 Filed 9–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4274–DR; Docket ID FEMA–2016–0001]

Oklahoma; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Oklahoma (FEMA–4274–DR), dated July 15, 2016, and related determinations.

DATES: Effective on August 24, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Oklahoma is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of July 15, 2016.

County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–21260 Filed 9–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4274–DR; Docket ID FEMA–2016–0001]

Oklahoma; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Oklahoma (FEMA–4274–DR), dated July 15, 2016, and related determinations.

EFFECTIVE DATE: August 30, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Oklahoma is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of July 15, 2016.

Jackson County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–21375 Filed 9–2–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket Nos. FR–6000–FA–30 and FR–6000–FA–33]

Announcement of Funding Awards: Housing Counseling Grants Fiscal Year 2016

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (42 U.S.C. 3545), this document notifies the public of Fiscal Year (FY) 2016 funding decisions made by the Department in competitions for funding under two Notices of Funding Availability (NOFA; the FY 2016 and 2017 Comprehensive Housing Counseling Grant Program NOFA and the FY 2016 and 2017 Housing Counseling Training Grant Program NOFA.

FOR FURTHER INFORMATION CONTACT: Brian Siebenlist, Director, Office of Policy and Grant Administration, Room 9224, Office of Housing Counseling, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone number 202–402–5415. Hearing- or speech-impaired individuals may access this number by calling the Federal Relay Service at telephone number 800–877–8339. (This is a toll-free number.)

SUPPLEMENTARY INFORMATION:

The Housing Counseling Program is authorized by Section 106 of the Housing and Urban Development Act of 1968 (12 U.S.C. 1701x). Consistent with this authority, HUD enters into agreement with qualified public or private nonprofit organizations to provide housing counseling services to low- and moderate-income individuals and families nationwide. The housing counseling services supported by the Housing Counseling Program include providing information and assistance to the homeless, renters, homebuyers, homeowners, and senior citizens in areas such as pre-purchase counseling, financial management, property maintenance and other forms of housing assistance to help individuals and families improve their housing conditions and meet the responsibilities of tenancy and homeownership.

HUD funding of housing counseling agencies is not guaranteed, and when funds are awarded, a HUD grant does not cover all expenses incurred by an agency to deliver housing counseling services. Counseling agencies must actively seek additional funds from other sources such as city, county, state and federal agencies and from private entities to ensure that they have sufficient operating funds. The availability of housing counseling grants depends upon appropriations and the outcome of the award competition.

In accordance with Section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, 42 U.S.C. 3545), today's **Federal Register** publication lists in Appendices A and B the names, addresses, and amounts of each award made under the FY 2016 and 2017 Comprehensive Housing Counseling NOFA and the FY 2016 and 2017 Housing Counseling Training NOFA, respectively. The requirements for the NOFAs are found in the following documents:

1. General Section to the Department's Fiscal Year 2016 NOFAs for Discretionary Programs, available at: *http://portal.hud.gov/hudportal/documents/huddoc?id=2016nofa-gensec.pdf*
2. Notice of Funding Availability for the Department's Fiscal Years 2016 and 2017 Comprehensive Housing Counseling Grant Program, available at: *http://portal.hud.gov/hudportal/documents/huddoc?id=2016chcnofa.pdf*
3. HUD's FY 2016—2017 Housing Counseling Training Grant Notice of Funding Availability, available at: *http://portal.hud.gov/hudportal/documents/huddoc?id=2016hctnofa.pdf.*

Applications were scored and selected for funding on the basis of selection criteria contained in the NOFAs. HUD awarded more than $40 million in comprehensive grants to support the housing counseling services of 31 national and regional organizations, five multi-state organizations, 17 State Housing Finance Agencies and 231 local housing counseling agencies. HUD awarded more than $2 million to four national organizations to provide accessible and affordable training of housing counselors. Appendices A and B list award recipients under each Housing Counseling Program NOFA.

The Catalog of Federal Domestic Assistance number for the Housing Counseling Program is 14.169.

Dated: August 22, 2016.

Edward L. Golding,

Principal Deputy Assistant Secretary for Housing.

Appendix A—List of FY 2016 Awardees for the FY 2016–2017 Comprehensive Housing Counseling NOFA

Intermediary Organizations (31)

CATHOLIC CHARITIES USA
2050 Ballenger Avenue
Suite 400
ALEXANDRIA, VA 22314–6847
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $951,150.00

CCCS OF GREATER ATLANTA—DBA CLEARPOINT CREDIT COUNSELING SOLUTIONS
270 Peachtree St, Suite 1800
ATLANTA, GA 30303–1217
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $1,394,427.00

CITIZENS' HOUSING AND PLANNING ASSOCIATION, INC.
18 Tremont Street,
Suite 401
BOSTON, MA 02108–2301
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $681,862.00

CONSUMER CREDIT COUNSELING SERVICES OF SAN FRANCISCO D/B/A BALANCE
595 Market St
Suite 920
SAN FRANCISCO, CA 94105–2802
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $528,492.00

GREENPATH, INC.
36500 Corporate Drive
FARMINGTON HILLS, MI 48331–3553
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $2,121,893.00

HOMEFREE—U S A
6200 Baltimore Avenue
RIVERDALE, MD 20737–1054
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $1,890,150.00

HOMEOWNERSHIP PRESERVATION FOUNDATION
7645 Lyndale Ave. South
Suite 250
MINNEAPOLIS, MN 55423–4084
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $953,027.00

HOUSING & COMMUNITY DEVELOPMENT NETWORK OF NEW JERSEY
145 West Hanover Street
TRENTON, NJ 08618–4823
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $257,837.00

HOUSING ACTION ILLINOIS
11 E. Adams St, Suite 1601
CHICAGO, IL 60603–6304
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $698,569.00

HOUSING PARTNERSHIP NETWORK
1 Washington Mall, 12th Fl
BOSTON, MA 02108–2603
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $840,041.00

MINNESOTA HOMEOWNERSHIP CENTER
1000 Payne Avenue
Suite 200
SAINT PAUL, MN 55130–3986
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $628,729.00

MISSISSIPPI HOMEBUYER EDUCATION CENTER—INITIATIVE
350 West Woodrow Wilson
Suite 3480
JACKSON, MS 39213–7681
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $328,871.00

MON VALLEY INITIATIVE
303–305 E. 8th Avenue
HOMESTEAD, PA 15120–1517
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $676,333.00

MONEY MANAGEMENT INTERNATIONAL INC.
14141 Southwest Fwy
Sugar Land, TX 77478–3493
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $1,288,565.00

MONTANA HOMEOWNERSHIP NETWORK DBA NEIGHBORWORKS MONTANA
509 1st Ave S
Great Falls, MT 59401–3604
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $392,140.00

NATIONAL ASSOCIATION OF REAL ESTATE BROKERS—INVESTMENT DIVISION, INC
7677 OakPort Street, Suite 1030, 10th Fl
OAKLAND, CA 94621–1929
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $891,284.00

NATIONAL CAPACD
1628 16th Street, NW
4th Floor
WASHINGTON, DC 20009–3064
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $582,731.00

NATIONAL COMMUNITY REINVESTMENT COALITION, INC.
727 15th St NW
Washington, DC 20005–2168
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $1,171,196.00

NATIONAL COUNCIL OF LA RAZA
1126 16th Street, NW., Suite 600
Raul Yzaguirre Building
WASHINGTON, DC 20036–4845
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $1,535,279.00

NATIONAL FOUNDATION FOR CREDIT COUNSELING, INC.
2000 M St. NW

Suite 505
WASHINGTON, DC 20036–3307
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $1,388,227.00

NATIONAL URBAN LEAGUE
120 Wall Street
7th Floor
NEW YORK, NY 10005–3904
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $954,370.00

NEIGHBORHOOD REINVESTMENT CORP. DBA NEIGHBORWORKS AMERICA
999 North Capital Street NE
Suite 900
WASHINGTON, DC 20002–4684
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $3,000,000.00

NEIGHBORHOOD STABILIZATION CORPORATION (NACA COUNSELING SUBSIDIARY)
225 Centre Street, Suite 100
BOSTON, MA 02119–1298
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $1,454,859.00

NEW YORK MORTGAGE COALITION
85 Broad Street
17th Floor
NEW YORK, NY 10004–2434
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $387,475.00

NORTH CAROLINA HOUSING COALITION
5800 Faringdon Place
RALEIGH, NC 27609–3930
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $576,379.00

NUEVA ESPERANZA, INC.
4261 N 5th St
Philadelphia, PA 19140–2615
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $563,093.00

PATHSTONE CORPORATION
400 East Avenue
ROCHESTER, NY 14607–1910
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $224,763.00

RURAL COMMUNITY ASSISTANCE CORPORATION
3120 Freeboard Drive
Suite 201
WEST SACRAMENTO, CA 95691–5039
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $708,376.00

TELAMON CORPORATION
5560 Munford Road
Suite 109
RALEIGH, NC 27612–2635
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $368,670.00

UNITED WAY OF CENTRAL ALABAMA, INC.
3600 8th Avenue
BIRMINGHAM, AL 35222–3250
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $263,748.00

WEST TENNESSEE LEGAL SERVICES, INCORPORATED
210 West Main Street
JACKSON, TN 38301–6114
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $704,242.00

Multi-State Organizations (5)

CREDIT ADVISORS FOUNDATION
1818 S. 72nd Street
OMAHA, NE 68124–1704
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $119,893.00

CREDIT CARD MGMT SVCS, INC D/B/A DEBTHELPER.COM
1325 N Congress Ave
#201
WEST PALM BEACH, FL 33401–2005
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $173,455.00

DEBT MANAGEMENT CREDIT COUNSELING CORP.
3310 N. Federal Highway
LIGHTHOUSE POINT, FL 33064–6742
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $108,414.00

OPERATION HOPE, INC
707 Wilshire Blvd. Suite 3030
LOS ANGELES, CA 90017–3582
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $200,000.00

TRANSFORMANCE (FORMERLY CCCS OF GREATER DALLAS)
8737 King George Drive
Suite 200
DALLAS, TX 75235–2222
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $184,245.00

State Housing Finance Agencies (17)

COLORADO HOUSING AND FINANCE AUTHORITY
1981 Blake St.
DENVER, CO 80202–1229
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $499,691.00

CONNECTICUT HOUSING FINANCE AUTHORITY
999 West Street
ROCKY HILL, CT 06067–3011
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $193,191.00

GEORGIA HOUSING AND FINANCE AUTHORITY
60 Executive Park South, NE
ATLANTA, GA 30329–2296
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $570,000.00

IDAHO HOUSING AND FINANCE ASSOCIATION
565 West Myrtle
BOISE, ID 83702–7675
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $230,194.00

KENTUCKY HOUSING CORPORATION
1231 Louisville Rd.
FRANKFORT, KY 40601–6156
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $306,062.00

LOUISIANA HOUSING CORPORATION
2415 Quail Drive
BATON ROUGE, LA 70808–0120
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $491,352.00

MAINE STATE HOUSING AUTHORITY
353 Water Street
AUGUSTA, ME 04330–4665
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $178,000.00

MICHIGAN STATE HOUSING DEVELOPMENT AUTHORITY
735 E. Michigan Avenue
LANSING, MI 48912–1474
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $482,134.00

MISSISSIPPI HOME CORPORATION
735 Riverside Drive
JACKSON, MS 39202–1166
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $312,688.00

NEW HAMPSHIRE HOUSING FINANCE AUTHORITY
32 Constitution Dr
Bedford, NH 03110–6062
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $249,333.00

NEW JERSEY HOUSING AND MORTGAGE FINANCE AGENCY
637 South Clinton Avenue
TRENTON, NJ 08611–1811
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $136,430.00

NEW YORK STATE HOUSING FINANCE AGENCY
38–40 State Street
4th Floor
ALBANY, NY 12207–2837
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $597,095.00

PENNSYLVANIA HOUSING FINANCE AGENCY
211 North Front Street
HARRISBURG, PA 17101–1406
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $1,366,258.00

SOUTH DAKOTA HOUSING DEVELOPMENT AUTHORITY
3060 E. Elizabeth Street
PIERRE, SD 57501–5876
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $233,760.00

VIRGIN ISLANDS HOUSING FINANCE AUTHORITY
3202 Demarara No.3 Frenchtown
No.3 Frenchtown Plaza
Suite 200
St. Thomas, VI 00802

Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,971.00

VIRGINIA HOUSING DEVELOPMENT AUTHORITY
601 S. Belvidere Street
RICHMOND, VA 23220–6504
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $1,040,918.00

WASHINGTON STATE HOUSING FINANCE COMMISSION
1000 2nd Avenue Suite 2700
SEATTLE, WA 98104–3601
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $411,356.00

Local Housing Counseling Agencies (181)

ACTION FOR BOSTON COMMUNITY DEVELOPMENT, INC.
178 Tremont St
Boston, MA 02111–1006
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $25,889.00

AFFORDABLE HOMEOWNERSHIP FOUNDATION INC
5264 Clayton Ct Ste 1
Fort Myers, FL 33907–2112
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,456.00

AFFORDABLE HOUSING ENTERPRISES, INC.
214 South 12th Street
GRIFFIN, GA 30224–2812
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,832.00

AFRICAN DEVELOPMENT CENTER OF MINNESOTA
1931 S 5th St
Minneapolis, MN 55454–1257
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $17,411.00

ALLEGANY COUNTY COMMUNITY OPPORTUNITIES AND RURAL DEVELOPMENT (ACCORD) CORP.
PO Box 573
Belmont, NY 14813–0573
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $23,890.00

APPALACHIAN HOUSING AND REDEVELOPMENT CORPORATION
PO Box 1428
Rome, GA 30162–1428
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $12,730.00

AREA COMMITTEE TO IMPROVE OPPORTUNITIES NOW, INC.
594 Oconee Street
ATHENS, GA 30605–1721
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,080.00

ARUNDEL COMMUNITY DEVELOPMENT SERVICE INC
2666 Riva Road
Suite 210
ANNAPOLIS, MD 21401–7345
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $22,385.00

ASIAN INCORPORATED
1167 Mission Street, 4th Floor
SAN FRANCISCO, CA 94103–1544
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,504.00

BAY AREA HOUSING, INC
114 Washington Ave
Bay City, MI 48708–5846
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,089.00

BEAUFORT COUNTY BLACK CHAMBER OF COMMERCE
801 Bladen Street
BEAUFORT, SC 29902–4574
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $23,388.00

BENNINGTON-RUTLAND OPPORTUNITY COUNCIL, INC. (BROC)
45 Union Street
RUTLAND, VT 05701–3956
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $24,809.00

BETTER NEIGHBORHOODS, INCORPORATED
120 Emmons St
Schenectady, NY 12304–2859
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,089.00

BRIGHT COMMUNITY TRUST, INC.
2605 Enterprise Road E. Suite 230
CLEARWATER, FL 33759–1067
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,539.00

BROWARD COUNTY HOUSING AUTHORITY
4780 N State Road 7
LAUDERDALE LAKES, FL 33319–5860
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,713.00

CAMPBELLSVILLE HOUSING AND REDEVELOPMENT AUTHORITY
400 Ingram Ave
PO Box 597
CAMPBELLSVILLE, KY 42718–1627
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $11,970.00

CATHOLIC CHARITIES DIOCESE OF ST. CLOUD
157 Roosevelt Rd Ste 200
Saint Cloud, MN 56301–5485
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,000.00

CATHOLIC SOCIAL SERVICES—FALL RIVER
PO Box M
Fall River, MA 02724–0388
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $14,987.00

CCCS OF ALABAMA—MONTGOMERY
640 South Lawrence Street
Farmer Wilson Building
MONTGOMERY, AL 36104–5810
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,466.00

CCCS OF KERN AND TULARE COUNTIES
2001 F Street
BAKERSFIELD, CA 93301–4237
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $15,906.00

CENTER FOR SIOUXLAND
715 Douglas St
Sioux City, IA 51101–1021
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $24,349.00

CENTRAL JERSEY HOUSING RESOURCE CENTER, INC.
600 1st Ave Ste 3
Raritan, NJ 08869–1346
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $14,500.00

CHELSEA RESTORATION CORPORATION
154 Pearl St Ofc 2
CHELSEA, MA 02150–2868
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,999.00

CHOCTAW HOUSING AUTHORITY
207 Jim Monroe Road
HUGO, OK 74743–5621
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $15,823.00

CITY OF BLOOMINGTON—HOUSING AND NEIGHBORHOOD DEVELOPMENT (HAND)
401 N Morton Street
BLOOMINGTON, IN 47404–3729
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $22,737.00

CITY OF FULTON COMMUNITY DEVELOPMENT AGENCY
125 West Broadway
FULTON, NY 13069–2215
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $17,494.00

CITY OF SAN ANTONIO/DEPARTMENT OF HUMAN SERVICES
106 S. Saint Marys St, 7th Floor
SAN ANTONIO, TX 78205–3601
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,716.00

CITY OF VACAVILLE DEPARTMENT OF HOUSING SERVICES
40 Eldridge Avenue Suite 2
VACAVILLE, CA 95688–6824
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $17,244.00

CLINCH-POWELL RESOURCE CONSERVATION AND DEVELOPMENT COUNCIL, INC
7995 Rutledge Pike
RUTLEDGE, TN 37861–3003
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $22,761.00

COMMUNITY ACTION AGENCY
1214 Greenwood Avenue

JACKSON, MI 49203–3037
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $27,501.00

COMMUNITY ACTION AGENCY OF NORTHWEST ALABAMA, INC.
745 Thompson St
Florence, AL 35630–3867
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,925.00

COMMUNITY ACTION AGENCY OF OKLAHOMA CITY AND OKLAHOMA/CANADIAN COUNTIES, INC.
319 SW 25th St
Oklahoma City, OK 73109–5921
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,492.00

COMMUNITY ACTION NETWORK, INC.
7891 Highway 69 S
Springville, TN 38256–5400
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,961.00

COMMUNITY ACTION PARTNERSHIP OF NORTH ALABAMA, INC.
1909 Central Pkwy SW
Decatur, AL 35601–6822
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,501.00

COMMUNITY ACTION PARTNERSHIP OF SUBURBAN HENNEPIN
8800 Highway 7 #401
ST LOUIS PARK, MN 55426–3929
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $32,952.00

COMMUNITY ACTION PARTNERSHIP, HUNTSVILLE/MADISON & LIMESTONE COUNTIES, INC
3516 Stringfield Rd NW
HUNTSVILLE, AL 35810–1758
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,080.00

COMMUNITY ACTION PROGRAM OF EVANSVILLE & VANDERBURGH COUNTY, INC
401 SE 6th St Ste 1
Evansville, IN 47713–1249
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,292.00

COMMUNITY CONNECTION OF NORTHEAST OREGON, INC.
2802 Adams Ave
La Grande, OR 97850–5267
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $17,244.00

COMMUNITY DEVELOPMENT & IMPROVEMENT CORP.
100 Rogers Terrace
AIKEN, SC 29801–3435
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,868.00

COMMUNITY DEVELOPMENT SUPPORT ASSOCIATION
2615 E Randolph Ave
Enid, OK 73701–4670
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,492.00

COMMUNITY ENTERPRISE INVESTMENTS, INCORPORATED
302 North Barcelona St
PENSACOLA, FL 32501–4806
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,877.00

COMMUNITY HOUSING AND SHELTER SERVICES
708 H Street, Ste. B
MODESTO, CA 95354–3436
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,706.00

COMMUNITY HOUSING INITIATIVE, INC
3033 College Wood Dr
Melbourne, FL 32934–8324
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,420.00

COMMUNITY HOUSING NETWORK, INC
570 Kirts Blvd. Suite 231
TROY, MI 48084–4156
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,749.00

COMMUNITY HOUSING SOLUTIONS
12114 Larchmere Blvd.
CLEVELAND, OH 44120–1139
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,951.00

COMMUNITY INVESTMENT CORPORATION OF DECATUR, INC
2121 S. Imboden Court
DECATUR, IL 62521–5286
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,749.00

COMMUNITY RENEWAL TEAM, INC.
330 Market Street
HARTFORD, CT 06120–2901
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $14,987.00

COMMUNITY SERVICE NETWORK, INC.
136 Elm Street
STONEHAM, MA 02180–3426
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,222.00

COMMUNITY SERVICE PROGRAMS OF WEST ALABAMA, INC.
601 Black Bears Way
Tuscaloosa, AL 35401–4807
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $22,678.00

COMMUNITY SERVICES AND EMPLOYMENT TRAINING, INC. (CSET)
312 NW 3rd Avenue
VISALIA, CA 93291–3626
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $15,823.00

COMMUNITY SERVICES LEAGUE
404 North Noland Road
INDEPENDENCE, MO 64050–3057
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,504.00

COMPASS FAMILY & COMMUNITY SERVICES
535 Marmion Ave
Youngstown, OH 44502–2323
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,373.00

COMPREHENSIVE HOUSING RESOURCES, INC.
21450 Gibralter Dr Ste 1
Port Charlotte, FL 33952–5417
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,247.00

CONSUMER CREDIT COUNSELING SERVICE OF CENTRAL OKLAHOMA
3230 N Rockwell Ave
Bethany, OK 73008–4034
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $30,176.00

CORPORACION DESARROLLO ECONOMICO, VIVIENDA Y SALUD
Calle Eugenio M. de Hostos #175
Esq Puro Girau
ARECIBO, PR 00612–4709
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,340.00

COUNTY OF BERGEN, DEPARTMENT OF HUMAN SERVICES, DIVISION OF SENIOR SERVICES
1 Bergen County Plz Fl 2
Hackensack, NJ 07601–7075
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,258.00

COUNTYCORP
130 W. Second Street
Suite 1420
DAYTON, OH 45402–1500
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,080.00

CRAWFORD SEBASTIAN COMMUNITY DEVELOPMENT COUNCIL
4831 Armour St.
FORT SMITH, AR 72904–4523
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,925.00

DIVERSIFIED HOUSING DEVELOPMENT, INC.
8025 Liberty Rd
Windsor Mill, MD 21244–2966
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,549.00

EAST DALLAS COMMUNITY ORGANIZATION
4210 Junius St Fl 5
Dallas, TX 75246–1429
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $14,611.00

EASTERN EIGHT COMMUNITY DEVELOPMENT CORP.
214 East Watauga Avenue
JOHNSON CITY, TN 37601–4630
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $22,301.00

EASTERN IOWA REGIONAL HOUSING AUTHORITY
7600 Commerce Park
DUBUQUE, IA 52002–9673

Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,644.00

ECONOMIC OPPORTUNITY FOR SAVANNAH CHATHAM COUNTY AREA, INC.
618 W Anderson St
SAVANNAH, GA 31415–5420
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $17,118.00

EDEN COUNCIL FOR HOPE AND OPPORTUNITY (ECHO)
770 A St
Hayward, CA 94541–3956
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,340.00

ELIZABETH CITY STATE UNIVERSITY COMMUNITY DEVELOPMENT PROGRAM
1704 Weeksville Rd.
ELIZABETH CITY, NC 27909–7977
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,466.00

FAIR HOUSING CONTACT SERVICE
441 Wolf Ledges Pkwy Ste 200
Akron, OH 44311–1038
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $23,113.00

FAIR HOUSING COUNCIL OF RIVERSIDE COUNTY, INC
3933 Mission Inn Ave
RIVERSIDE, CA 92501–3219
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $29,072.00

FAIR HOUSING OF MARIN
1314 Lincoln Ave.
SAN RAFAEL, CA 94901–2105
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,247.00

FAIR HOUSING RESOURCE CENTER
1100 Mentor Ave
PAINESVILLE, OH 44077–1832
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $28,630.00

FAMILY HOUSING ADVISORY SERVICES, INC.
2401 Lake St
Omaha, NE 68111–3872
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $22,092.00

FOOTHILLS CREDIT COUNSELING, INC.
709 W Main St
SUITE A
Forest City, NC 28043–2820
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $22,277.00

FREDERICK COMMUNITY ACTION AGENCY
100 S Market St
FREDERICK, MD 21701–5527
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $24,701.00

GAP COMMUNITY DEVELOPMENT RESOURCES, INC.
129 West Fowlkes Street
Suite 137
FRANKLIN, TN 37064–3561
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,916.00

GARRETT COUNTY COMMUNITY ACTION COMMITTEE INC.
104 E Center St Apt 3
Oakland, MD 21550–1341
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $23,680.00

GRAND RAPIDS URBAN LEAGUE
745 Eastern Ave SE
Grand Rapids, MI 49503–5544
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $17,411.00

GREATER LANSING HOUSING COALITION
600 W Maple St
Lansing, MI 48906–5093
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,713.00

HABITAT FOR HUMANITY OF JACKSONVILLE, INC.
2404 Hubbard Street
JACKSONVILLE, FL 32206–2911
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,658.00

HABITAT FOR HUMANITY, STANISLAUS COUNTY
630 Kearney Avenue
MODESTO, CA 95350–5714
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $22,301.00

HAGERSTOWN NEIGHBORHOOD DEVELOPMENT PARTNERSHIP, INC. (HNDP)
21 E Franklin St
Hagerstown, MD 21740–4914
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,089.00

HARFORD COUNTY HOUSING AGENCY
15 S Main St Ste 106
Bel Air, MD 21014–8723
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $23,865.00

HIGH PLAINS COMMUNITY DEVELOPMENT CORP.
803 E. 3rd St Ste 4
CHADRON, NE 69337–2855
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $26,725.00

HISPANIC ASSOCIATION OF CONTRACTORS AND ENTERPRISES
167 W Allegheny Ave
Philadelphia, PA 19140–5846
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $23,137.00

HISPANIC BROTHERHOOD OF ROCKVILLE CENTRE, INC.
59 Clinton Ave
Rockville Centre, NY 11570–4042
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $17,787.00

HOME DEVELOPMENT RESOURCES, INC.
430 Prior Street SE
GAINESVILLE, GA 30501–3402
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $13,858.00

HOME OPPORTUNITIES MADE EASY, INC. (HOME, INC.)
1111 Ninth Street, Suite 210
DES MOINES, IA 50314–2527
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,749.00

HOME OWNERSHIP RESOURCE CENTER OF LEE COUNTY
2915 Colonial Blvd. Ste 200
Fort Myers, FL 33966–1009
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,575.00

HOME PARTNERSHIP, INC. (HPI)
626 Towne Center Dr
Suite 102
Joppa, MD 21085–4446
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $17,620.00

HOOSIER UPLANDS ECONOMIC DEVELOPMENT CORPORATION
500 W Main St
MITCHELL, IN 47446–1411
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,549.00

HOUSING ASSISTANCE AND DEVELOPMENT SERVICES, INC.
215 E 12th Ave
BOWLING GREEN, KY 42101–3403
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,456.00

HOUSING AUTHORITY OF MINGO COUNTY
5026 Helena Avenue
Delbarton, WV 25670
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $12,730.00

HOUSING AUTHORITY OF YAMHILL COUNTY
135 NE Dunn Pl
McMinnville, OR 97128–9081
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,089.00

HOUSING AUTHORITY OF THE CITY OF GREENSBORO D/B/A GREENSBORO HOUSING AUTHORITY
450 N Church St
Greensboro, NC 27401–2001
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $80,662.00

HOUSING AUTHORITY OF THE CITY OF HIGH POINT
500 E Russell Ave
High Point, NC 27260–6746
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,501.00

HOUSING AUTHORITY OF THE CITY OF JACKSON
2747 Livingston Rd
Jackson, MS 39213–6928
Grant Type: COMPREHENSIVE COUNSELING

Amount Awarded: $19,877.00

HOUSING AUTHORITY OF THE CITY OF PATERSON
60 Van Houten St
Paterson, NJ 07505–1028
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,501.00

HOUSING AUTHORITY OF THE CITY OF PRICHARD
200 W. Prichard Avenue
Prichard, AL 36610–0307
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $15,906.00

HOUSING COUNSELING SERVICES, INCORPORATED
2410 17th St NW Ste 100
Washington, DC 20009–2724
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $67,782.00

HOUSING EDUCATION AND ECONOMIC DEVELOPMENT, INC.
3405 Medgar Evers Blvd.
Jackson, MS 39213–6360
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $29,047.00

HOUSING INITIATIVE PARTNERSHIP, INC. (“HIP”)
6525 Belcrest Road
Suite 555
HYATTSVILLE, MD 20782–2003
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $29,800.00

HOUSING PARTNERS OF TULSA, INCORPORATED
415 E. Independence Street
TULSA, OK 74106–5727
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $14,694.00

HOUSING SERVICES MID MICHIGAN (FORMERLY HOUSING SERVICES FOR EATON COUNTY)
319 S Cochran Ave
Charlotte, MI 48813–1555
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $22,009.00

IN AFFORDABLE HOUSING, INCORPORATED
108 South Rodney Parham
LITTLE ROCK, AR 72205–4708
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $23,739.00

INTERCOMMUNITY ACTION, INC. D/B/A INTERACT, JOURNEY’S WAY
403 Rector St
Philadelphia, PA 19128–3522
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $14,694.00

JACKSONVILLE AREA LEGAL AID, INC.
126 W Adams St
Jacksonville, FL 32202–3849
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,044.00

JEFFERSON COUNTY HOUSING AUTHORITY
3700 Industrial Parkway
BIRMINGHAM, AL 35217–5316
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $13,482.00

JONESBORO URBAN RENEWAL AND HOUSING AUTHORITY HOUSING AND COMMUNITY DEVELOPMENT ORGANIZATION (JURHA HCDO)
330 Union St
Jonesboro, AR 72401–2815
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,501.00

KANAWHA INSTITUTE FOR SOCIAL RESEARCH & ACTION, INC.
131 Perkins Ave
DUNBAR, WV 25064–1433
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $13,942.00

KCEOC COMMUNITY ACTION PARTNERSHIP, INC.
PO Box 490
Barbourville, KY 40906–0490
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,163.00

LAKE COUNTY HOUSING AUTHORITY
33928 North U.S. Highway 45
GRAYSLAKE, IL 60030–1714
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,006.00

LATIN UNITED COMMUNITY HOUSING ASSOCIATION
3541 W. North Avenue
CHICAGO, IL 60647–4808
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $22,301.00

LEE COUNTY HOUSING DEVELOPMENT CORPORATION
PO Box 2854
Fort Myers, FL 33902–2854
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $15,823.00

LIMA ALLEN COUNCIL ON COMMUNITY AFFAIRS
540 S. Central Ave.,
LIMA, OH 45804–1306
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $17,787.00

LINCOLN HILLS DEVELOPMENT CORPORATION
302 Main St
TELL CITY, IN 47586–2207
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,877.00

LIVE THE DREAM DEVELOPMENT, INC
247 Double Springs Road
BOWLING GREEN, KY 42101–5160
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $14,987.00

MACOUPIN COUNTY HOUSING AUTHORITY
760 Anderson Street
CARLINVILLE, IL 62626–1003
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,115.00

MANATEE COMMUNITY ACTION AGENCY, INC. F/K/A MANATEE OPPORTUNITY COUNCIL, INCORPORATED
302 Manatee Ave E Ste 200
BRADENTON, FL 34208–1900
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,373.00

MARKETVIEW HEIGHTS ASSOCIATION, INC.
308 North Street
ROCHESTER, NY 14605–2540
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,337.00

MARYLAND RURAL DEVELOPMENT CORPORATION
101 Cedar Lane
PO Box 739
GREENSBORO, MD 21639–1580
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $17,996.00

METRO–INTERFAITH HOUSING MANAGEMENT CORPORATION DBA METRO INTERFAITH SERVICES
21 New St.
BINGHAMTON, NY 13903–1759
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $14,987.00

MIAMI BEACH COMMUNITY DEVELOPMENT CORP
945 Pennsylvania Ave
Miami Beach, FL 33139–5482
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $12,730.00

MID-FLORIDA HOUSING PARTNERSHIP, INC.
1834 Mason Ave
Daytona Beach, FL 32117–5101
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,044.00

MISSISSIPPI COUNTY, ARKANSAS ECONOMIC OPPORTUNITY COMMISSION, INC.
1400 North Division Street
BLYTHEVILLE, AR 72315–1438
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $15,154.00

MOVIN’ OUT, INC.
902 Royster Oaks Drive Ste 105
MADISON, WI 53714–9101
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,925.00

MUNCIE HOME OWNERSHIP AND DEVELOPMENT CENTER
120 West Charles Street
MUNCIE, IN 47305–2419
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,832.00

MUSCATINE MUNICIPAL HOUSING AGENCY
2806 Bloomington Lane
MUSCATINE, IA 52761–6135
Grant Type: COMPREHENSIVE COUNSELING

Amount Awarded: $19,125.00
NATIVE AMERICAN YOUTH AND FAMILY CENTER
5135 NE Columbia Blvd.
Portland, OR 97218–1201
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $12,730.00
NCCS CENTER FOR NONPROFIT HOUSING
6308 S. Warner
FREMONT, MI 49412–9279
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $12,730.00
NEVADA PARTNERS, INC.
710 W Lake Mead Blvd.
North Las Vegas, NV 89030–4067
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,797.00
NEWTOWN COMMUNITY DEVELOPMENT CORPORATION
511 W University Dr Ste 4
Tempe, AZ 85281–5585
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,961.00
NIAGARA FALLS NEIGHBORHOOD HOUSING SERVICES
479 16th St
NIAGARA FALLS, NY 14303–1636
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,501.00
NORTH HUDSON COMMUNITY ACTION CORPORATION
800 31st St
Union City, NJ 07087–2428
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,115.00
NORTHERN PUEBLOS HOUSING AUTHORITY
5 W Gutierrez Ste 10
Santa Fe, NM 87506–0956
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,115.00
NORTHWEST MICHIGAN COMMUNITY ACTION AGENCY, INC
3963 Three Mile Road, North
TRAVERSE CITY, MI 49686–9164
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $23,890.00
OAKLAND COUNTY HOUSING COUNSELING
250 Elizabeth Lake Rd Ste 1900
Pontiac, MI 48341–1035
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $28,229.00
OAKLAND LIVINGSTON HUMAN SERVICE AGENCY
196 Cesar E Chavez Ave
Pontiac, MI 48342–1094
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,125.00
OCEAN COMMUNITY ECONOMIC ACTION NOW, INC. (O.C.E.A.N., INC.)
2008 Route 37
TOMS RIVER, NJ 08753–7183
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,842.00
OPA–LOCKA COMMUNITY DEVELOPMENT CORPORATION
490 Opa Locka Blvd.
Opa Locka, FL 33054–3563
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,337.00
OPEN COMMUNITIES
614 Lincoln Avenue
WINNETKA, IL 60093–2331
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $15,070.00
OPEN DOOR COUNSELING CENTER
34420 SW Tualatin Valley Hwy
Hillsboro, OR 97123–5470
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $31,656.00
ORANGE COUNTY FAIR HOUSING COUNCIL, INC
1516 Brookhollow Drive
Suite A
SANTA ANA, CA 92705–5426
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $15,237.00
ORGANIZED COMMUNITY ACTION PROGRAM, INC
507 North Three Notch Street
TROY, AL 36081–2120
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,121.00
PENNSYLVANIA COMMUNITY REAL ESTATE CORP. D/B/A TENANT UNION REPRESENTATIVE NETWORK (T.U.R.N.)
21 S 12th St Ste 1100
Philadelphia, PA 19107–3610
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,256.00
PRO–HOME, INC.
40 Summer Street
TAUNTON, MA 02780–3420
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,466.00
PROJECT SENTINEL
554 Valley Way
MILPITAS, CA 95035–4106
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $27,268.00
PROVIDENCE HOUSING AUTHORITY
100 Broad St
Providence, RI 02903–4154
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $17,244.00
RALEIGH AREA DEVELOPMENT AUTHORITY, INC.
4030 Wake Forest Road
Suite 205
RALEIGH, NC 27609–6800
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,504.00
REFUGEE FAMILY ASSISTANCE PROGRAM
5405 Memorial Drive Suite 101
STONE MOUNTAIN, GA 30083–3234
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,292.00
ROCKAWAY DEVELOPMENT AND REVITALIZATION CORPORATION
1920 Mott Ave
Suite 2
FAR ROCKAWAY, NY 11691–4106
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $18,456.00
SANDHILLS COMMUNITY ACTION PROGRAM, INC.
340 Commerce Avenue, Suite 20
SOUTHERN PINES, NC 28387–7168
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $22,527.00
SHORE UP!, INC
520 Snow Hill Rd
SALISBURY, MD 21804–6031
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,575.00
SMART MONEY HOUSING AKA SMART WOMEN SMART MONEY
3510 West Franklin Blvd.
CHICAGO, IL 60624–1316
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $37,393.00
SOLITA'S HOUSE INC
3101 E. 7th Ave.
TAMPA, FL 33605–4207
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $23,137.00
SOUTHERN APPALACHIAN LABOR SCHOOL FOUNDATION, INC.
140 School Street
OAK HILL, WV 25901–2932
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $17,411.00
SOUTHERN BANCORP COMMUNITY PARTNERS
8924 Kanis Rd
Little Rock, AR 72205–6414
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $17,327.00
SOUTHERN MARYLAND TRI-COUNTY COMMUNITY ACTION
8383 Old Leonardtown Road
Hughesville, MD 20637
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $22,678.00
SOUTHERN MINNESOTA REGIONAL LEGAL SERVICES, INC.
55 5th St E Ste 400
Saint Paul, MN 55101–1118
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $26,397.00
SOUTHERN NEVADA REGIONAL HOUSING AUTHORITY (SNRHA)
340 N 11th St
Las Vegas, NV 89101–3125
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,115.00
SOUTHEASTERN HOUSING FOUNDATION

986 Doyle Street
ORANGEBURG, SC 29115–6087
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,868.00

SPRINGFIELD HOUSING AUTHORITY
200 N 11th St
Springfield, IL 62703–1004
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $12,730.00

STATESVILLE HOUSING AUTHORITY
110 W Allison St
Statesville, NC 28677–6616
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,575.00

STRYCKER'S BAY NEIGHBORHOOD COUNCIL, INC.
696 Amsterdam Avenue
NEW YORK, NY 10025–6901
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $13,106.00

SUMMECH COMMUNITY DEVELOPMENT CORPORATION, INC.
633 Pryor Street
ATLANTA, GA 30312–2738
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,856.00

TAMPA BAY COMMUNITY DEVELOPMENT CORPORATION
2139 NE Coachman Rd
Clearwater, FL 33765–2612
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $22,385.00

TENANT RESOURCE CENTER
1202 Williamson St Ste 102
MADISON, WI 53703–4806
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,964.00

THE AFFORDABLE HOUSING CORPORATION OF MARION, INDIANA
812 S Washington St
Marion, IN 46953–1967
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $23,890.00

THE AGRICULTURE AND LABOR PROGRAM, INC.
300 Lynchburg Road
LAKE ALFRED, FL 33850–2576
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $15,363.00

TOTAL RESOURCE COMMUNITY DEVELOPMENT ORGANIZATION
1415 West 104th Street
CHICAGO, IL 60643–2962
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,835.00

TWIN RIVERS OPPORTUNITIES, INC.
318 Craven St.
NEW BERN, NC 28560–4909
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,549.00

UNITED NEIGHBORS, INC.
808 Harrison Street
DAVENPORT, IA 52803–5000
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $16,115.00

UNIVERSAL HOUSING DEVELOPMENT CORPORATION
301 E 3rd St
Russellville, AR 72801–5109
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,549.00

UTAH STATE UNIVERSITY—FAMILY LIFE CENTER—HFC
493 N 700 E
Logan, UT 84321–4231
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $25,889.00

WACO COMMUNITY DEVELOPMENT CORPORATION
1624 Colcord Ave
Waco, TX 76707–2246
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,337.00

WEST PALM BEACH HOUSING AUTHORITY
1715 Division Ave
West Palm Beach, FL 33407–6284
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,713.00

WESTERN PIEDMONT COUNCIL OF GOVERNMENTS
1880 2nd Ave NW
HICKORY, NC 28601–5766
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $28,772.00

WESTMORELAND COMMUNITY ACTION
226 S Maple Ave
Greensburg, PA 15601–3234
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $15,823.00

WILL COUNTY CENTER FOR COMMUNITY CONCERNS
2455 Glenwood Ave
Joliet, IL 60435–5464
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $28,713.00

WORKING IN NEIGHBORHOODS
1814 Dreman Ave
Cincinnati, OH 45223–2319
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,173.00

WSOS COMMUNITY ACTION COMMISSION, INC.
109 S Front St
FREMONT, OH 43420–3021
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $24,892.00

YOUNGSTOWN METROPOLITAN HOUSING AUTHORITY
131 W Boardman St
Youngstown, OH 44503–1337
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $20,713.00

YOUNGSTOWN NEIGHBORHOOD DEVELOPMENT CORP.
820 Canfield Road
YOUNGSTOWN, OH 44511–2345
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $19,585.00

YOUTH EDUCATION AND HEALTH IN SOULARD
1901 S 11th St
Saint Louis, MO 63104–3915
Grant Type: COMPREHENSIVE COUNSELING
Amount Awarded: $21,901.00

Appendix B—List of FY 2016 Awardees for the FY 2016–2017 Housing Counseling Training NOFA

Intermediary Organizations (4)

NATIONAL COMMUNITY REINVESTMENT COALITION, INC.
727 15th St NW
Washington, DC 20005–2168
Grant Type: TRAINING
Amount Awarded: $457,778.00

NATIONAL COUNCIL OF LA RAZA
1126 16th Street, NW., Suite 600
Raul Yzaguirre Building
WASHINGTON, DC 20036–4845
Grant Type: TRAINING
Amount Awarded: $607,948.00

NEIGHBORHOOD REINVESTMENT CORP. DBA NEIGHBORWORKS AMERICA
999 North Capital Street NE
Suite 900
WASHINGTON, DC 20002–4684
Grant Type: TRAINING
Amount Awarded: $757,995.00

RURAL COMMUNITY ASSISTANCE CORPORATION
3120 Freeboard Drive
Suite 201
WEST SACRAMENTO, CA 95691–5039
Grant Type: TRAINING
Amount Awarded: $387,625.00

[FR Doc. 2016–21230 Filed 9–2–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FW–HQ–LE–2016–N150; FF09L00200–FX–LE18110900000]

Proposed Information Collection; Federal Fish and Wildlife Permit Applications and Reports—Law Enforcement

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (U.S. Fish and Wildlife Service) will ask the Office of Management and Budget (OMB) to approve the information collection (IC) described below. As required by the Paperwork Reduction Act of 1995 and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this

opportunity to comment on this IC. This IC is scheduled to expire on December 31, 2016. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: To ensure that we are able to consider your comments on this IC, we must receive them by November 7, 2016.

ADDRESSES: Send your comments on the IC to the Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or *tina_campbell@fws.gov* (email). Please include "1018–0092" in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this IC, contact Tina Campbell at *tina_campbell@fws.gov* (email) or 703–358–2676 (telephone).

SUPPLEMENTARY INFORMATION:

I. Abstract

The Endangered Species Act (ESA) (16 U.S.C. 1531 *et seq.*) makes it unlawful to import or export fish, wildlife, or plants without obtaining prior permission as deemed necessary for enforcing the ESA or upholding the Convention on International Trade in Endangered Species (CITES) (see 16 U.S.C. 1538(e)). This information collection includes the following permit/license application forms:

(1) FWS Form 3–200–2 (Designated Port Exception Permit). Under 50 CFR 14.11, it is unlawful to import or export wildlife or wildlife products at ports other than those designated in 50 CFR 14.12 unless you qualify for an exception. These exceptions allow qualified individuals, businesses, or scientific organizations to import or export wildlife or wildlife products at a nondesignated port:

(a) When the wildlife or wildlife products will be used as scientific specimens.

(b) To minimize deterioration or loss.

(c) To relieve economic hardship.

To request an import or export of wildlife or wildlife products at nondesignated ports, applicants must complete FWS Form 3–200–2. Designated port exception permits are valid for 2 years. We may require a permittee to file a report on activities conducted under authority of the permit.

(2) FWS Form 3–200–3 (Import/Export License). It is unlawful to import or export wildlife or wildlife products for commercial purposes without first obtaining an import/export license (50 CFR 14.91). Applicants must complete FWS Form 3–200–3 to request this license. We use the information that we collect on the application as an enforcement tool and management aid to (a) monitor the international wildlife market and (b) detect trends and changes in the commercial trade of wildlife and wildlife products. Import/export licenses are valid for 1 year. We may require a licensee to file a report on activities conducted under authority of the import/export license.

Permittees and licensees must maintain records that accurately describe each importation or exportation of wildlife or wildlife products made under the license, and any additional sale or transfer of the wildlife or wildlife products. In addition, licensees must make these records and the corresponding inventory of wildlife or wildlife products available for our inspection at reasonable times, subject to applicable limitations of law. We believe the burden associated with these recordkeeping requirements is minimal because the records already exist. Importers and exporters must complete FWS Form 3–177 (Declaration for Importation or Exportation of Fish or Wildlife) for all imports or exports of wildlife or wildlife products. This form provides an accurate description of the imports and exports. OMB has approved the information collection for FWS Form 3–177 and assigned OMB Control Number 1018–0012. Normal business practices should produce records (*e.g.,* invoices or bills of sale) needed to document additional sales or transfers of the wildlife or wildlife products.

II. Data

OMB Control Number: 1018–0092.

Title: Federal Fish and Wildlife Permit Applications and Reports—Law Enforcement, 50 CFR 13 and 14.

Service Form Number: 3–200–2 and 3–200–3.

Type of Request: Extension of a currently approved collection.

Description of Respondents: Individuals, businesses, scientific institutions, and State, local, or tribal governments.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Activity	Number of respondents	Number of responses	Completion time per response (hours)	Total annual burden hours *
3–200–2: application and recordkeeping	1,398	1,398	1.25	1,748
3–200–2: report	5	5	1	5
3–200–3: application and recordkeeping	9,351	9,351	1.25	11,689
3–200–3: report	5	5	1	5
Totals	10,759	10,759		13,447

* *rounded.*

Estimated Annual Nonhour Burden Cost: None.

III. Comments

We invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this IC. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: August 31, 2016.

Tina A. Campbell,

Chief, Division of Policy, Performance, and Management Programs, U.S. Fish and Wildlife Service.

[FR Doc. 2016–21336 Filed 9–2–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2016–N122; FXES11120800000–156–FF08EVEN00]

Low-Effect Habitat Conservation Plan for the Mount Hermon June Beetle, Santa Cruz County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received an application from the County of Santa Cruz for an 11-year incidental take permit under the Endangered Species Act of 1973, as amended (Act). The application addresses the potential for "take" of the federally endangered Mount Hermon June beetle likely to occur incidental to the construction of a multi-use facility and associated infrastructure at the existing juvenile detention center in Felton, Santa Cruz County, California. We invite comments from the public on the application package, which includes a Low-Effect Habitat Conservation Plan for the Mount Hermon June Beetle.

DATES: To ensure consideration, please send your written comments by October 6, 2016.

ADDRESSES: You may download a copy of the Habitat Conservation Plan, draft Environmental Action Statement and Low-Effect Screening Form, and related documents on the Internet at *http://www.fws.gov/ventura/*, or you may request copies of the documents by U.S. mail to our Ventura office or by phone (see **FOR FURTHER INFORMATION CONTACT**). Please address written comments to Stephen P. Henry, Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003. You may alternatively send comments by facsimile to (805) 644–3958.

FOR FURTHER INFORMATION CONTACT: Chad Mitcham, Fish and Wildlife Biologist, by U.S. mail to the Ventura office, or by telephone at (831) 768–7794.

SUPPLEMENTARY INFORMATION: We have received an application from the County of Santa Cruz for an 11-year incidental take permit under the Act. The application addresses the potential for "take" of the federally endangered Mount Hermon June beetle (*Polyphylla barbata*) likely to occur incidental to the construction of a multi-use facility and associated infrastructure at the existing juvenile detention center, at the County of Santa Cruz Juvenile Hall, 3650 Graham Hill Road (APN: 061–371–16), Felton, Santa Cruz County, California. We invite comments from the public on the application package, which includes the Low-Effect Habitat Conservation Plan for the Mount Hermon June Beetle. This proposed action has been determined to be eligible for a Categorical Exclusion under the National Environmental Policy Act of 1969, as amended.

Background

The U.S. Fish and Wildlife Service (Service) listed the Mount Hermon June beetle as endangered on January 24, 1997 (62 FR 3616). Section 9 of the Act (16 U.S.C. 1531 *et seq.*) and its implementing regulations prohibit the take of fish or wildlife species listed as endangered or threatened. "Take" is defined under the Act to include the following activities: "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct" (16 U.S.C. 1532); however, under section 10(a)(1)(B) of the Act, we may issue permits to authorize incidental take of listed species. The Act defines "Incidental Take" as take that is not the purpose of carrying out of an otherwise lawful activity. Regulations governing incidental take permits for threatened and endangered species are provided at 50 CFR 17.32 and 17.22, respectively. Issuance of an incidental take permit must not jeopardize the existence of federally listed fish, wildlife, or plant species.

Take of listed plants is not prohibited under the Act unless such take would violate State law. As such, take of plants cannot be authorized under an incidental take permit. Plant species may be included on a permit in recognition of the conservation benefits provided them under a habitat conservation plan. All species, including plants, covered by the incidental take permit receive assurances under our "No Surprises" regulations (50 CFR 17.22(b)(5) and 17.32(b)(5)). In addition to meeting other specific criteria, actions undertaken through implementation of the Habitat Conservation Plan (HCP) must not jeopardize the continued existence of federally listed animal or plant species.

Applicant's Proposal

The County of Santa Cruz (hereafter, the applicant) has submitted a Low-Effect HCP in support of their application for an incidental take permit (ITP) to address take of the Mount Hermon June beetle that is likely to occur as the result of direct impacts on up to 0.189-acre (ac) (8,225 square feet (sf)) of degraded sandhills habitat occupied by the species. Take would be associated with the construction of a multi-use facility on an existing parcel legally described as Assessor Parcel Number: 061–371–16. The current site address is 3650 Graham Hill Road in Felton, Santa Cruz County, California. The applicant is requesting a permit for take of Mount Hermon June beetle that would result from "covered activities" that are related to the construction of the multi-use facility and associated infrastructure.

The applicant proposes to avoid, minimize, and mitigate take of Mount Hermon June beetle associated with the covered activities by fully implementing the HCP. The following measures will be implemented: (1) Temporary fencing and signs will be installed to clearly delineate the boundaries of the project; (2) if construction occurs during the flight season (considered to be between May and October, annually), exposed soils will be covered with erosion control fabric or other impervious materials to prevent any dispersing Mount Hermon June beetles from burrowing into exposed soil at the construction site; (3) employment of a Service-approved entomologist to capture and relocate into suitable habitat and out of harm's way any Mount Hermon June beetle larvae unearthed during construction activities; (4) all new outdoor night lighting will use light bulbs certified not to attract nocturnally active insects, in order to minimize disruption of Mount Hermon June beetle breeding behavior during the adult flight season; and (5) Option 1: Enhance 4.3 ac (187,308 sf) of habitat on site for a 10-year period; or, Option 2: Secure off-site mitigation at a ratio of 1:1 to mitigate for permanent habitat impacts through the acquisition of 0.189 ac (8,225 sf) of conservation credits at the Zayante Sandhills Conservation Bank. The applicant will fund up to $81,995 to ensure implementation of all minimization measures, monitoring, and reporting requirements identified in the HCP.

In the proposed HCP, the applicant considers two alternatives to the proposed action: "No Action" and "Redesigned Project." Under the "No Action" alternative, an ITP for the multi-use facility would not be issued. The multi-use facility would not be built, and the enhancement of habitat on site or the purchase of conservation credits would not be provided to effect recovery actions for Mount Hermon June beetle. Additionally, State of California Title 15 and Title 24 standards for recreation and physical activity space for juvenile facilities would not be met. Because of State requirements and because the proposed action results in a net benefit for the covered species, the No Action Alternative has been rejected. Under the "Redesigned Project" alternative, the project would be redesigned to take place within existing impervious surfaces, avoiding impacts to suitable habitat for the species. The Redesigned Project would not meet State of California Title 15 and Title 24 standards and would not contribute to the long-term recovery of the species through enhancement of habitat or the purchase of conservation credits. As such, the "Project Redesign" alternative has also been rejected.

Our Preliminary Determination

We are requesting comments on our preliminary determination that the applicant's proposal will have a minor or negligible effect on the Mount Hermon June beetle and that the plan qualifies as a low-effect HCP as defined by our Habitat Conservation Planning Handbook (November 1996). We base our determinations on three criteria: (1) Implementation of the proposed project as described in the HCP would result in minor or negligible effects on federally listed, proposed, and/or candidate species and their habitats; (2) implementation of the HCP would result in minor or negligible effects on other environmental values or resources; and (3) HCP impacts, considered together with those of other past, present, and reasonably foreseeable future projects, would not result in cumulatively significant effects. In our analysis of these criteria, we have made a preliminary determination that the approval of the HCP and issuance of an ITP qualify for categorical exclusion under the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), as provided by the Department of the Interior implementing regulations in part 46 of title 43 of the Code of Federal Regulations (43 CFR 46.205, 46.210, and 46.215). However, based upon our review of public comments that we receive in response to this notice, this preliminary determination may be revised.

Next Steps

We will evaluate the permit application, including the plan and comments we receive, to determine whether the application meets the requirements of section 10(a)(1)(B) of the Act. We will also evaluate whether issuance of the ITP would comply with section 7(a)(2) of the Act by conducting an intra-Service Section 7 consultation.

Public Review

We provide this notice under section 10(c) of the Act and the National Environmental Policy Act of 1969, as amended (NEPA), NEPA's public involvement regulations (40 CFR 1500.1(b), 1500.2(d), and 1506.6). We are requesting comments on our determination that the applicants' proposal will have a minor or neglible effect on the Mount Hermon June beetle and that the plan qualifies as a low-effect HCP as defined by our 1996 Habitat Conservation Planning Handbook. We will evaluate the permit application, including the plan and comments, we receive, to determine whether the application meets the requirements of section 10(a)(1)(B) of the Act. We will use the results of our internal Service consultation, in combination with the above findings, in our final analysis to determine whether to issue the permits. If the requirements are met, we will issue an ITP to the applicant for the incidental take of Mount Hermon June beetle. We will make the final permit decision no sooner than 30 days after the date of this notice.

Public Comments

If you wish to comment on the permit applications, plans, and associated documents, you may submit comments by any one of the methods in **ADDRESSES**.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public view, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10 of the Act (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6).

Dated: August 26, 2016.

Stephen P. Henry,

Field Supervisor, Ventura Fish and Wildlife Office, Ventura, California.

[FR Doc. 2016–21286 Filed 9–2–16; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–FHC–2016–N141; FXFR1334088TWG0W4–123–FF08EACT00]

Trinity River Adaptive Management Working Group; Public Meeting, Teleconference, and Web-Based Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce a public meeting of the Trinity River Adaptive Management Working Group (TAMWG). The TAMWG is a Federal advisory committee that affords stakeholders the opportunity to give policy, management, and technical input concerning Trinity River (California) restoration efforts to the Trinity Management Council (TMC). The TMC interprets and recommends policy, coordinates and reviews management actions, and provides organizational budget oversight.

DATES: *Public meeting, Teleconference, and Web-based meeting:* TAMWG will meet from 9:30 a.m. to 4 p.m. Pacific Time on Monday, September 26, 2016, and from 9:30 a.m. to 3 p.m. Pacific Time on Tuesday, September 27, 2016. *Submitting Information:* If you wish to submit written information or questions for the TAMWG to consider during the meeting, you must contact Elizabeth Hadley (**FOR FURTHER INFORMATION CONTACT**) no later than September 16, 2016.

ADDRESSES: *Meeting:* The meeting will be held at the Trinity River Restoration Program Office, 1313 South Main Street, Weaverville, CA 96093. *Teleconference:* The call in number: 866–715–1246, and the participant pass code is: 4251781. *Web-based meeting: http://www.mymeetings.com/nc/join.php?sigKey=mymeetings&i=442336293&p=&t=c*

FOR FURTHER INFORMATION CONTACT: Joseph C. Polos, by mail at U.S. Fish and Wildlife Service, 1655 Heindon Road, Arcata, CA 95521; by telephone at 707–

822–7201 or by email at *joe_polos@fws.gov* or Elizabeth W. Hadley, Redding Electric Utility, by mail at 777 Cypress Avenue, Redding, CA 96001; by telephone at 530–339–7308 or by email at *ehadley@reupower.com.* Individuals with a disability may request an accommodation by sending an email to either point of contact.

SUPPLEMENTARY INFORMATION: In accordance with the requirements of the Federal Advisory Committee Act, 5 U.S.C. App., we announce that the Trinity River Adaptive Management Working Group will hold a meeting. The TAMWG affords stakeholders the opportunity to give policy, management, and technical input concerning Trinity River (California) restoration efforts to the Trinity Management Council (TMC). The TMC interprets and recommends policy, coordinates and reviews management actions, and provides organizational budget oversight.

Meeting Agenda

- Designated Federal Officer (DFO) update;
- TMC Chair update;
- Executive Director Updates;
- Trinity River Restoration Program (TRRP) Outmigrant Monitoring;
- TRRP Bird Monitoring;
- TRRP Compliance Monitoring;
- TRRP Flow Scheduling Process;
- Letters from members of the public;
- Issues identified at joint TAMWG/TMC meeting;
- Current TMC Issues; and
- Public comment.

The final agenda will be posted on the Internet at *http://www.fws.gov/arcata.*

Public Input

Interested members of the public may submit relevant information or questions for the TAMWG to consider during the meeting. Written statements must be received by the date listed in **DATES**, so that the information may be available to the TAMWG for their consideration prior to this meeting. Written statements must be supplied to Elizabeth Hadley in one of the following formats: One hard copy with original signature, one electronic copy with original signature, and one electronic copy via email (acceptable file formats are Adobe Acrobat PDF, MS Word, PowerPoint, or rich text file).

Registered speakers who wish to expand on their oral statements, or those who wished to speak but could not be accommodated on the agenda, may submit written statements to Elizabeth Hadley up to 7 days after the meeting.

Meeting Minutes

Summary minutes of the meeting will be maintained by Elizabeth Hadley (see **FOR FURTHER INFORMATION CONTACT**). The minutes will be available for public inspection within 14 days after the meeting, and will be posted on the TAMWG Web site at *http://www.fws.gov/arcata.*

Dated: August 30, 2016.

Joseph C. Polos,

Supervisory Fish Biologist, Arcata Fish and Wildlife Office, Arcata, California.

[FR Doc. 2016–21289 Filed 9–2–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[14X LLIDC00100 L16530000.IB0000 LA.DM.DI6M0000]

Notice of Mailing/Street Address Change for the BLM-Cottonwood Field Office

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The mailing/street address for the Bureau of Land Management (BLM) Cottonwood Field Office will be changing from 1 Butte Drive, Cottonwood, Idaho 83522 to 2 Butte Drive, Cottonwood, Idaho 83522.

DATES: The date for the change will be on or about August 26, 2016.

FOR MORE INFORMATION CONTACT: Richard Alvarez, Lead Property Management Specialist, BLM Idaho State Office, (208) 373–3916, *ralvarez@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to leave a message or question for Mr. Alvarez. The FIRS is available 24 hours a day, seven days a week.

You will receive a reply during normal business hours.

Authority: Departmental Manual 382, Chapter 2.1.

Peter J. Ditton,

Acting BLM Idaho State Director.

[FR Doc. 2016–21341 Filed 9–2–16; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCAN038000 L17110000.EB0000 16X LXSIWLDS0000]

Notice of Individual Special Recreation Permit Requirement in the King Range National Conservation Area, California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) provides notice of a new Individual Special Recreation Permit (ISRP) requirement for overnight use in the King Range Wilderness and Backcountry Management Zone (King Range Wilderness). The ISRP will limit the number of persons entering the King Range Wilderness for overnight use to 60 persons/day during the peak season (May 15-September 15), and 30 persons/day during the non-peak season (September 16-May 14). This action will limit overnight use of the King Range Wilderness for the first time. Day use entries will not be limited. The ISRP program will be administered through an electronic reservation system. The ISRP requirement results from analysis and planning direction provided by the 2012 King Range Wilderness and Rocks and Islands Wilderness Areas Management Plan (WMP), and the 2005 King Range National Conservation Area Resource Management Plan (RMP) both of which outline operational goals of the area and the purpose of a wilderness permit program.

DATES: The BLM's Arcata Field Office intends to implement the King Range Wilderness ISRP program, which will be administered through the electronic reservation system, Recreation.gov, with a projected go-live date in January 2017.

ADDRESSES: Additional information may be obtained by email request to *CA338@blm.gov,* or by mail to Bureau of Land Management, King Range Project Office, PO Drawer 189, Whitethorn, CA 95589, attention NCA Manager. Copies of the King Range WMP and King Range RMP are available in the King Range Project Office, 768 Shelter Cove Road, Whitethorn, CA and Arcata Field Office, 1695 Heindon Rd., Arcata, CA, 95521 and online at: *http://www.blm.gov/ca/st/en/prog/nlcs/King_Range_NCA.html.*

FOR FURTHER INFORMATION CONTACT: Benjamin Blom, NCA Manager, 707–825–2310, or Justin Robbins, Outdoor Recreation Planner, 707–986–5403. Persons who use a telecommunication device for the deaf (TDD) may call the Federal Information Relay Service

(FIRS) at 1–800–877–8339 to contact the above individuals during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The King Range NCA is a popular recreation and wilderness area and has received substantial Federal investment. Visitor use of the King Range Wilderness has almost doubled since completion of the King Range and Rocks and Islands Wilderness Management Plan in 2012, and has nearly tripled since wilderness designation in 2006.

In 2005, the BLM recognized the need to consider regulating overnight use in the King Range to protect wilderness character in the development of the King Range RMP. The RMP directed the BLM to establish visitor capacities in what is now the King Range Wilderness to manage for solitude and to reduce crowding at overnight camping locations. In combination with other actions, managing the total visitor load will maintain opportunities for solitude at most overnight locations and meet the intent of the Wilderness Act.

The Northern California Coastal Wild Heritage Wilderness Act of 2006 designated the 43,625-acre King Range Wilderness, as well as the Rocks and Islands Wilderness (all rocks and islands within three miles of the King Range coastline). A 2.5-mile coastal strip of the King Range NCA Backcountry Management Zone, which extends north from the wilderness boundary to the Mattole Trailhead, was not designated as part of the King Range Wilderness but is included in this new ISRP requirement. The King Range Wilderness and Rocks and Islands Wilderness Management Plan (WMP, 2012) specified a range of management actions to achieve visitor capacity and visitor load objectives, primarily by limiting daily visitor entries into the King Range Wilderness. The WMP also outlines implementation of an additional range of management actions to manage visitor use should limitations on daily entries not achieve visitor load objectives within the wilderness. Although the target of 60 starts per day (and estimated visitor load of 192 people at one time) may seem limited in a 43,625 acre wilderness area with over 80 miles of trails, analysis has shown that more than 80–90% percent of visitor use is concentrated along the 1,200 acres that comprise the northern coastal section of the Lost Coast Trail. The BLM is committed to finding the proper balance between public use and resource protection.

Authority: 16 U.S.C. 6803(b) and 43 CFR 2932.13.

Thomas Pogacnik,

Deputy State Director, Bureau of Land Management.

[FR Doc. 2016–21340 Filed 9–2–16; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States of America v. Iron Mountain Inc., et al.; Public Comment and Response on Proposed Final Judgment

Pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), the United States hereby publishes below the comment received on the proposed Final Judgment in *United States of America* v. *Iron Mountain Inc., et al.,* Civil Action No. 1:16–cv–00595–APM, together with the Response of the United States to Public Comment.

Copies of the comment and the United States' Response are available for inspection on the Antitrust Division's website at *http://www.justice.gov/atr,* and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Patricia A. Brink,

Director of Civil Enforcement.

United States District Court for the District of Columbia

United States of America, Plaintiff, v. *Iron Mountain Inc.,* and *Recall Holdings Ltd., Defendants.*

Civil Action No. 1:16–cv–00595–APM Judge Amit P. Mehta

Response of the United States to Public Comment on the Proposed Final Judgment

Pursuant to the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b)–(h) ("APPA" or "Tunney Act"), the United States hereby responds to a single public comment received regarding the proposed Final Judgment in this case. After consideration of the submitted comment, the United States continues to believe that the proposed Final Judgment provides an effective and appropriate remedy for the antitrust violations alleged in the Complaint. The United States will move the Court for entry of the proposed Final Judgment after the public comment and this Response have been published in the **Federal Register** pursuant to 15 U.S.C. § 16(d).

I. Background

On March 31, 2016, the United States filed the Complaint in this matter, alleging that defendant Iron Mountain Inc.'s ("Iron Mountain") acquisition of defendant Recall Holdings Ltd. ("Recall") likely would substantially lessen competition in the provision of hard-copy records management services in several markets in the United States in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18. The Complaint further alleged that, as a result of the acquisition as originally proposed, prices for these services likely would have increased and customers would have received services of lower quality.

At the same time the Complaint was filed, the United States filed a proposed Final Judgment, a Hold Separate Stipulation and Order, and a Competitive Impact Statement ("CIS") that explains how the proposed Final Judgment is designed to remedy the likely anticompetitive effects of the proposed acquisition. As required by the Tunney Act, the United States published the proposed Final Judgment and CIS in the **Federal Register** on April 11, 2016. *See* 81 Fed. Reg. 21,383 (Apr. 11, 2016). In addition, the United States ensured that a summary of the terms of the proposed Final Judgment and CIS, together with directions for the submission of written comments, were published in *The Washington Post* on seven different days during the period of April 4, 2016, to April 10, 2016. *See* 15 U.S.C. § 16(c). The 60-day waiting period for public comments ended on June 10, 2016. One comment was received and is described below and attached as Exhibit 1.

II. The Investigation and Proposed Resolution

After Iron Mountain and Recall announced their plans to merge, the United States conducted an investigation into the competitive effects of the proposed transaction. The United States considered the potential competitive effects of the transaction on hard-copy records management services ("RMS") in a number of geographic areas. As a part of this investigation, the United States obtained documents and information from the merging parties and others and conducted more than 160 interviews with customers, competitors, and other individuals knowledgeable about the industry.

RMS involves the off-site storage of records and the provision of services related to records storage. For a variety of legal and business reasons, companies frequently must keep hard-copy records for significant periods of time. Given the physical space required to store any substantial volume of records and the effort required to manage stored records, many customers contract with RMS vendors such as Iron Mountain and Recall to provide these services. RMS vendors typically pick up records from customers and bring them to a secure off-site facility, where they index the records to allow their customers to keep track of them. RMS vendors retrieve stored records for customers upon request and often perform other services related to the storage, tracking, and shipping of records. For example, they sometimes destroy stored records on behalf of the customer once preservation is no longer required.

Customers often procure RMS through competitive bidding and have contracts that usually specify fees for each service provided (*e.g.*, pick-up, monthly storage, retrieval, delivery, and transportation). Most customers purchase RMS in only one city. Customers with operations in multiple cities sometimes purchase RMS from a single vendor pursuant to a single contract. But, other multi-city customers purchase RMS under separate contracts for each city, often using different vendors in different cities.

The provision of RMS generally occurs in localized markets in a radius around a metropolitan area. Customers generally require a potential RMS vendor to have a storage facility located within a certain proximity to the customers' locations. Customers generally will not consider vendors located outside a particular radius, because the vendor will not be able to retrieve and deliver records on a timely basis. The travel radius a customer is willing to consider is usually measured in time, rather than miles, as retrieval of records is often a time-sensitive matter. Transportation costs also likely render a distant RMS vendor uncompetitive with vendors located closer to the customer.

After its investigation, the United States concluded that the proposed transaction likely would substantially lessen competition in the provision of RMS in 15 metropolitan areas: Detroit, Michigan; Kansas City, Missouri; Charlotte, North Carolina; Durham, North Carolina; Raleigh, North Carolina; Buffalo, New York; Tulsa, Oklahoma; Pittsburgh, Pennsylvania; Greenville/Spartanburg, South Carolina; Nashville, Tennessee; San Antonio, Texas; Richmond, Virginia; San Diego, California; Atlanta, Georgia; and Seattle, Washington. In each of these geographic areas, Iron Mountain and Recall are two of only a few significant firms providing RMS. As explained more fully in the Complaint and the CIS, in each of these areas, the resulting substantial increase in concentration and loss of head-to-head competition between Iron Mountain and Recall likely would result in higher prices and lower quality service for RMS customers in each of the relevant metropolitan areas. Complaint ¶ 18; CIS § II(B).

The proposed Final Judgment is designed to address competitive concerns in each of these 15 metropolitan areas. The proposed Final Judgment contemplates divesting Recall assets in 13 metropolitan areas to Access CIG, LLC ("Access") and Recall assets in the remaining two metropolitan areas (Atlanta and Seattle) to Acquirers who will be identified to and approved by the United States in the future. Divestiture of the assets to independent, economically viable competitors will ensure that customers of these services will continue to receive the benefits of competition.

The proposed Final Judgment requires the divestiture of over 26 Recall facilities, together with associated assets, including customer contracts. With respect to customer contracts, the proposed Final Judgment addresses the situation in which a Recall customer has records stored in more than one metropolitan area, which are covered by the same contract, and as a result of the divestitures, a portion of their records will be stored by Defendants and another portion will be stored by an Acquirer. Section II.L of the proposed Final Judgment defines these customers as "Split Multi-City Customers." To protect the interests of Split Multi-City Customers, Section IV.J of the proposed Final Judgment allows Split Multi-City Customers to terminate or otherwise modify their existing Recall contracts to enable them to transfer their records from an RMS facility retained by Defendants to a facility owned by an Acquirer without paying permanent withdrawal fees, retrieval fees, or other fees required under their contracts with Recall. This will ensure that the Acquirer of the Divestiture Assets can compete to provide RMS to customers that are served by both divested RMS facilities and RMS facilities retained by Defendants.

III. Standard of Judicial Review

The Tunney Act requires that proposed consent judgments in antitrust cases brought by the United States be subject to a 60-day public comment period, after which the court shall determine whether entry of the proposed Final Judgment "is in the public interest." 15 U.S.C. § 16(e)(1). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

> (A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
> (B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. § 16(e)(1). In considering these statutory factors, the court's inquiry is necessarily a limited one as the government is entitled to "broad discretion to settle with the defendant within the reaches of the public interest." *United States* v. *Microsoft Corp.*, 56 F.3d 1448, 1461 (D.C. Cir. 1995); *see also United States* v. *SBC Commc'ns, Inc.*, 489 F. Supp. 2d 1, 10–11 (D.D.C. 2007) (assessing public-interest standard under the Tunney Act); *United States* v. *InBev N.V./S.A.*, No. 08-cv-1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (discussing nature of review of consent judgment under the Tunney Act; inquiry is limited to "whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanisms to enforce the final judgment are clear and manageable").

Under the APPA, a court considers, among other things, the relationship between the remedy secured and the specific allegations set forth in the Complaint, whether the decree is sufficiently clear, whether the enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See Microsoft*, 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the decree, a court may not "engage in an unrestricted evaluation of what relief would best serve the public." *United States* v. *BNS, Inc.*, 858 F.2d 456, 462 (9th Cir. 1988) (citing *United States* v. *Bechtel Corp.*, 648 F.2d 660, 666 (9th Cir. 1981)). Instead, courts have held that:

> [t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is "*within the reaches of the public interest.*" More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).

In determining whether a proposed settlement is in the public interest, "the court 'must accord deference to the government's predictions about the efficacy of its remedies.'" *United States* v. *U.S. Airways Grp., Inc.,* 38 F. Supp. 3d 69, 76 (D.D.C. 2014) (quoting *SBC Commc'ns,* 489 F. Supp. 2d at 17); *see also Microsoft,* 56 F.3d at 1461 (noting that the government is entitled to deference as to its "predictions as to the effect of the proposed remedies"); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant due respect to the United States' "prediction as to the effect of the proposed remedies, its perception of the market structure, and its views of the nature of the case"); *United States* v. *Morgan Stanley,* 881 F. Supp. 2d 563, 567–68 (S.D.N.Y. 2012) (explaining that the government is entitled to deference in choice of remedies).

Courts "may not require that the remedies perfectly match the alleged violations." *SBC Commc'ns,* 489 F. Supp. 2d at 17. Rather, the ultimate question is whether "the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.'" *Microsoft,* 56 F.3d at 1461. Accordingly, the United States "need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms." *SBC Commc'ns,* 489 F. Supp. 2d at 17; *see also United States* v. *Apple, Inc.,* 889 F. Supp. 2d 623, 631 (S.D.N.Y. 2012). And a "proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is within the reaches of the public interest." *United States* v. *Am. Tel. & Tel. Co.,* 552 F. Supp. 131, 151 (D.D.C. 1982) (citations and internal quotations omitted); *see also United States* v. *Alcan Aluminum Ltd.,* 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy).

In its 2004 amendments to the Tunney Act,[1] Congress made clear its intent to preserve the practical benefits of using consent decrees in antitrust enforcement, adding the unambiguous instruction that "[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene." 15 U.S.C. § 16(e)(2). The procedure for the public-interest determination is left to the discretion of the court, with the recognition that the court's "scope of review remains sharply proscribed by precedent and the nature of the Tunney Act proceedings." *SBC Commc'ns,* 489 F. Supp. 2d at 11; *see also United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 17 (D.D.C. 2000) ("[T]he Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to public comments alone."); *US Airways,* 38 F. Supp. 3d at 76 (same).

IV. Summary of Public Comment and the Response of the United States

A. Summary of NRC's Comment

During the 60-day public comment period, the United States received one comment from National Records Centers, Inc. ("NRC"). NRC is a nationwide RMS provider that competes with the Defendants and Access in multiple metropolitan areas. NRC asserts that the "proposed acquisition will have an anticompetitive effect and a detrimental impact on the customers of Iron Mountain, Recall, and Access throughout the United States" and urges the United States to "re-think the Iron Mountain/Recall merger in its totality," and block the merger.

In the alternative, NRC urges modification of the proposed Final Judgment to allow all Recall customers affected by the merger to transfer their records to any RMS provider without penalty. NRC believes the proposed Final Judgment limits customer choice by forcing customers to switch to Access as the divestiture buyer (or to another approved Acquirer). NRC argues that, in lieu of requiring divestitures to Access (or to another Acquirer), the United States "should just simply allow those customers affected by the merger out of their contracts, without penalty, should they choose to do so" such that customers could select their RMS vendor instead of "staying with [Defendants] or going to [Access or another Acquirer]."

NRC also proposes two modifications to the proposed Final Judgment and contends the proposed definition of Split Multi-City Customer is overly restrictive. First, NRC argues that Split Multi-City Customers should be allowed to terminate their contracts with Defendants without penalty under Section IV.J and switch to NRC or some other RMS vendor. NRC would also extend the period for a customer to elect to move its records without penalty under Section IV.J from one to three years. Second, NRC proposes that the definition of Split Multi-City Customer be broadened by deleting the following from Section II.L: "A Split Multi-City Customer does not include a Recall customer that has separate contracts for each Recall facility in which it stores records."

B. Response of the United States to NRC's Comment

1. Divestitures in the 15 Relevant Geographic Markets Are Sufficient To Preserve Competition

NRC complains that limiting divestitures to 15 geographic areas is not enough to protect competition. However, because competition for the provision of RMS generally occurs in localized markets in a radius around a metropolitan area, requiring divestitures in those local geographic areas in which the transaction would result in substantial increase in concentration and loss of head-to-head competition between Iron Mountain and Recall is appropriate to preserve competition.

As described in Section II above, because of a strong customer desire for timely pick-up and delivery of records, customers typically procure services from RMS vendors located within the same metropolitan area as the customer. RMS vendors located outside a given local geographic area generally are considered by customers to be located too far away to be a viable RMS vendor. Further, RMS vendors located outside the local geographic area generally are unable to compete effectively as the distance from the customer's locations to the RMS vendor's facilities render the RMS vendor uncompetitive on price as well as service. Even large customers that choose one vendor across multiple local geographic areas generally require the single RMS vendor to be present in all of the local geographic areas where the customer is located. Accordingly, the United States focused on the potential competitive impact of the transaction on the local geographic level.

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[1] The 2004 amendments substituted "shall" for "may" in directing relevant factors for courts to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. *Compare* 15 U.S.C. § 16(e) (2004) *with* 15 U.S.C. § 16(e)(1) (2006); *see also SBC Commc'ns,* 489 F. Supp. 2d at 11 (concluding that the 2004 amendments "effected minimal changes" to Tunney Act review).

Over the course of its investigation, the United States determined that the proposed acquisition likely would lessen competition in 15 local geographic markets that are identified in the Complaint. The United States did not identify a competitive problem in any other geographic markets where Iron Mountain and Recall compete. Because Defendants agreed to a divestiture remedy to address the competitive issues in the 15 relevant geographic markets, the United States determined that blocking the merger was not necessary and that requiring divestitures in the affected 15 relevant geographic markets is sufficient to protect competition.

2. Access Is an Appropriate Buyer for the Divested Assets

NRC complains that Access is not an appropriate buyer for the Divestiture Assets. Access is a multi-city RMS vendor and the third-largest RMS vendor nationally, but it lacks RMS facilities in the 13 metropolitan areas where it is acquiring RMS facilities from the Defendants. Because Access lacked RMS facilities in these areas, it was not a viable competitive alternative to Iron Mountain or Recall to serve customer locations in these areas. The divestiture of Recall's RMS assets to Access in these areas establishes Access as a viable competitor in those areas and, thus, maintains existing competition that would otherwise be lost. The proposed Final Judgment does not direct Defendants to sell divestiture assets in the remaining two areas—Seattle and Atlanta—to Access, as Access is a significant competitor in these areas.

While the identity of the Acquirer or Acquirers of the assets in Seattle and Atlanta has yet to be determined, any proposed Acquirer will be subject to the United States' approval under Section IV of the proposed Final Judgment. Pursuant to Section IV.L, Defendants must divest the Divestiture Assets in such a way as to satisfy the United States that the assets can and will be operated by the purchasers as viable, ongoing records management businesses that can compete effectively in the relevant markets. Because Access (and other Acquirers) will effectively replace the lost competition, the proposed Final Judgment is in the public interest. *See Microsoft,* 56 F.3d at 1459–61 (noting that the government has discretion to settle "within the reaches of the public interest").

3. Limiting the Right To Terminate Recall Contracts to Customers in the 15 Relevant Geographic Markets Is Sufficient To Preserve Competition

NRC proposes a modification to Section IV.J to grant all Recall customers, wherever they are located, the right to terminate their contracts with Recall without penalty in order to switch to NRC or some other RMS vendor. The proposed Final Judgment is not designed to assist NRC or other RMS vendors to obtain Recall customers. The purpose of the proposed Final Judgment is to ensure that the Acquirers of the Divested Assets will be viable, ongoing RMS businesses that can compete effectively in the 15 relevant geographic markets. Because the United States determined that the transaction would likely lead to competitive harm in 15 local geographic areas, the proposed Final Judgment is designed only to address competitive harm to customers who are served in some capacity by Defendants' RMS facilities located in the 15 relevant geographic markets alleged in the Complaint. NRC's proposal would expand the scope of the decree beyond the 15 relevant geographic markets alleged in the Complaint. Including all Recall customers outside the 15 markets would far exceed what is necessary to remedy the harm found by the United States and alleged in the Complaint. *See Microsoft,* 56 F.3d at 1459–60 (discussing nature of review of consent decrees as limited to the allegations made).

4. The Definition of Split Multi-City Customers Is Appropriate for the Preservation of Competition

NRC proposes that the last sentence of Section II.L of the proposed Final Judgment, which states that "[a] Split Multi-City Customer does not include a Recall customer that has separate contracts for each Recall facility in which it stores records," be struck. The proposed Final Judgment is designed to allow customers with the preference for a single vendor pursuant to a single contract to transfer their records such that the records will not be stored at facilities managed by different vendors (*i.e.,* Iron Mountain and an Acquirer of the Divestiture Assets). As noted above, some customers prefer to use a single vendor pursuant to a single contract for all their RMS needs, while other customers use separate contracts for different metropolitan areas. The proposed Final Judgment limits this right to customers who have expressed this preference by having a single contract with a single vendor. The proposed Final Judgment does not include customers who have chosen to disaggregate their RMS business with separate contracts for each metropolitan area in which they store records. The contracts for disaggregated customers will either be divested or retained by Defendants, as appropriate, depending on whether each contract covers services in one of the 15 relevant geographic markets where harm is alleged. For that reason, the definition of Split Multi-City Customers is an effective and appropriate remedy for the antitrust violations alleged in the Complaint. *See Microsoft,* 56 F.3d at 1459–61 (discussing government's "broad discretion to settle with the defendant within the reaches of the public interest").

5. Allowing Split Multi-City Customers One Year To Transfer Records Is Appropriate for the Preservation of Competition

NRC proposes that Split Multi-City Customers be allowed to transfer their records to any RMS provider for a period of three years rather than the one-year period allowed under Section IV.J. The goal of the divestitures is to allow for the divested assets to be operated as viable, ongoing businesses that can compete effectively in the relevant markets. It is in the best interest of the industry and competition that any period of disruption or uncertainty in the relevant markets be minimized. For these reasons, limiting to a one-year period the right of Split Multi-City Customers to transfer their records provides an effective and appropriate remedy for the antitrust violations alleged in the Complaint. *See Microsoft,* 56 F.3d at 1459–61 (discussing government's "broad discretion to settle with the defendant within the reaches of the public interest").

V. Conclusion

After reviewing the one public comment, the United States continues to believe that the proposed Final Judgment provides an effective and appropriate remedy for the antitrust violations alleged in the Complaint, and is in the public interest. The United States will move this Court to enter the Final Judgment soon after the comment and this Response are published in the **Federal Register**.

Dated: August 29, 2016

Respectfully submitted,

__________/s/__________

Soyoung Choe
U.S. Department of Justice, Antitrust Division
Networks & Technology Enforcement Section

450 Fifth Street NW., Suite 7100
Washington, DC 20530
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Certificate of Service

I hereby certify that on this 29th day of August, 2016, the foregoing Notice of Extension of Time was filed using the Court's CM/ECF system, which shall send notice to all counsel of record.

_________/s/_________
Soyoung Choe
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May 31, 2016

Via Federal Express
United States Department of Justice
450 Fifth Street
Suite 7100
Washington, DC 20530

Attn: Maribeth Petrizzi
Chief Litigation II Section
Antitrust Division

Dear Sirs/Madam:

Please accept these public comments from Robert S. Moran, Jr., the undersigned, a partner of the law firm of McBreen & Kopko in connection with the pending matter captioned United States vs. Iron Mountain Inc. ("Iron Mountain") and Recall Holdings Ltd. ("Recall"); Proposed Final Judgment and Competitive Impact Statement Civil Action No. 1–16–cv–00595. Please be advised that the undersigned represents National Records Centers, Inc. ("NRC") a nationwide provider of records management services ("RMS") throughout the United States. NRC competes directly with Iron Mountain, Recall and Access CIG, LLC ("Access") in many markets.

It is our position that the proposed acquisition will have an anticompetitive effect and a detrimental impact on the customers of Iron Mountain, Recall and Access throughout the United States. NRC urges the Department of Justice to completely re-think the Iron Mountain/Recall merger in its totality. Combining the number one company in the industry with the number two company is unfair and anticompetitive by its very nature. Approving such an anticompetitive combination of businesses by merely causing business number two to shed some of its business is clearly not enough to result in open and fair competition. Forcing divestiture of this business to the number three company in the industry makes no sense at all. Instead of forcing this divestiture to a huge and growing company, the Department of Justice should just simply allow those customers affected by the merger out of their contracts, without penalty, should they chose to do so. Then those customers could pick their service provider by price and service and not be forced with the unhappy choice of staying with company two or going to company three. Customers are much better served with choices. The foundation of our pro-competition philosophy is choice. The Department of Justice should not engineer a Proposed Final Judgment that serves to limit customer choices.

It is our further position that the Proposed Final Judgment requires changes, at a minimum, to make it more equitable and to address our anti-competitive concerns.

First, we see no reason why *any* customer of Recall (not just a "Split-City Customer") should not have the right to terminate its contract with Recall without penalty. This is fair and reasonable.

Second, the definition for "Split Multi-City Customer" is overly restrictive. The definition used in the Proposed Final Judgment contains the qualification that "a Split Multi-City Customer does not include a Recall customer that has separate contracts for each Recall facility in which it stores records". It is our belief that this qualifying statement should be deleted from the Split Multi-City Customer definition.

In the Proposed Final Judgment Section IV "Divestitures", subparagraph J it is provided that for a period of one (1) year from the date of the sale of any Divestiture Assets to an Acquirer, defendant shall allow any Split Multi-City Customer to terminate or otherwise modify its contract with Recall so as to enable the Split Multi-City Customer to transfer some or all of its records to that Acquirer without penalty or delay and shall not enforce any contractual provision providing for permanent withdrawal fees, retrieval fees, or other fees associated with transferring such customers' records from a Recall Management Facility to a facility operated by Acquirer".

We see no reason why provision J does not allow that any Split Multi-City Customer can have the discretion to terminate or otherwise modify its contract with Recall so as to enable the Split Multi-City Customer to transfer some or all of its records to any other person or entity engaged in the records management business and not solely to Access. In this way fair and open competition for the business of any Split Multi-City Customer would occur allowing either Access or any other service provider to win the business. The substantial benefit to any Split Multi-City Customer is obvious. To restrict the discretion of these Split Multi-City Customers so that they have to do business with Access is unfair and inequitable. Also the qualification to the definition of Split Multi-City Customer further has anti-competitive affects and restricts open and fair competition.

It is our sincere hope that the acquisition of Recall by Iron Mountain not go forward. If it were to go forward then Recall customers in the affected markets should be free (without penalty) to choose *any* new service provider. Should the Department of Justice move forward with this Proposed Final Judgment, NRC strongly encourages the Department of Justice to modify the proposed Final Judgment in two ways. First, to delete the qualification to the definition of Split Multi-City Customer and second, to modify Provision IV Subsection J to enlarge the period from one (1) year to three (3) years and to allow any Split Multi-City Customer to terminate or otherwise modify its contract with Recall so as to enable the Split Multi-City Customer to transfer its records without penalty or delay to *any* records storage provider and *not only to Access.*

The foregoing is submitted respectfully and in the interest of fair and open competition to enhance the opportunity for any records storage company to obtain the business that is being divested as part of this proposed Final Judgment.

Thank you.

Very truly yours,

/s/ ____________________
Robert S. Moran, Jr.
RSM:km

[FR Doc. 2016–21287 Filed 9–2–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Fisher Clinical Services, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefor, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before October 6, 2016. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before October 6, 2016.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on June 17, 2016, Fisher Clinical Services, Inc., 7554 Schantz Road, Allentown, Pennsylvania 18106 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Schedule
Methylphenidate (1724)	II
Levorphanol (9220)	II
Noroxymorphone (9668)	II
Tapentadol (9780)	II

The company plans to import the listed substances for analytical research, testing, and clinical trials. This authorization does not extend to the import of finished FDA approved or non-approved dosage form for commercial distribution in the United States.

The company plans to import an intermediate form of tapentadol (9780) to bulk manufacture tapentadol for distribution to its customers. Placement of this drug code onto the company’s registration does not translate into automatic approval of subsequent permit applications to import controlled substances. Approval of permit applications will occur only when the registrant’s business activity is consistent with what is authorized under to 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016–21240 Filed 9–2–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Cody Laboratories, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before November 7, 2016.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on May 18, 2016, Cody Laboratories, Inc., 601 Yellowstone Avenue, Cody, Wyoming 82414 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Dihydromorphine (9145)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333).	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Hydrocodone (9193)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Morphine (9300)	II
Thebaine (9333)	II
Oxymorphone (9652)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Tapentadol (9780)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016–21238 Filed 9–2–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Isosciences

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before November 7, 2016.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal

Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (''Deputy Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on May 3, 2016, Isosciences, LLC, 1017 West Ninth Avenue, Building 10, Suite B, King of Prussia, Pennsylvania 19406 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
Lysergic acid diethylamide (7315)	I
3,4-Methylenedioxyamphetamine (7400).	I
3,4-Methylenedioxy-N-ethylamphetamine (7404).	I
3,4-Methylenedioxymethamphetamine (7405).	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Codeine (9050)	II
Morphine (9300)	II

The company plans to manufacture small quantities of the listed controlled substances to make reference standards which will be distributed to their customers.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016–21241 Filed 9–2–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Unither Manufacturing, LLC

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before October 6, 2016. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before October 6, 2016.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (''Deputy Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on May 6, 2016, Unither Manufacturing, LLC., 331 Clay Road, Rochester, New York 14623 applied to be registered as an importer of methylphenidate (1724), a basic class of controlled substance listed in schedule II.

The company plans to import the listed substance solely for updated analytical testing purposes for EU customer requirements.

This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016–21239 Filed 9–2–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: AMRI Rensselaer, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before November 7, 2016.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (''Deputy Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on May 19, 2016, AMRI Rensselaer, Inc., 33 Riverside Avenue, Rensselaer, New York 12144 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Marihuana (7360)	I

Controlled substance	Schedule
Tetrahydrocannabinols (7370)	I
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Pentobarbital (2270)	II
4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333)	II
Meperidine (9230)	II
Fentanyl (9801)	II

The company plans to manufacture bulk controlled substances for use in product development and for distribution to its customers.

In reference to drug codes 7360 (marihuana) and 7370 (THC), the company plans to bulk manufacture these drugs as synthetics. No other activities for these drug codes are authorized for this registration.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016–21242 Filed 9–2–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0010]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection U.S. Official Order Forms for Schedules I and II Controlled Substances DEA Form 222

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** at 81 FR 42726, June 30, 2016, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for an additional 30 days until October 6, 2016.

FOR FURTHER INFORMATION CONTACT: If you have comments on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* U.S. Official Order Forms for Schedules I and II Controlled Substances.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* DEA Form: 222. The applicable component within the Department of Justice is the Drug Enforcement Administration, Office of Diversion Control.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected public (Primary): Business or other for-profit.

Affected public (Other): Not-for-profit institutions; Federal, State, local, and tribal governments.

Abstract: The Controlled Substances Act (CSA) (21 U.S.C. 801–971) establishes a closed system of distribution for controlled substances. To this end, controlled substances are closely monitored and tightly regulated as they are distributed through the supply chain. One tool that helps to maintain the closed system of distribution is the CSA provision that states it "shall be unlawful for any person to distribute a controlled substance in schedules I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) of this section.." 21 U.S.C. 828(a).

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The DEA estimates that 125,435 registrants participate in this information collection, taking an estimated 11.6 hours per registrant annually.

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates that this collection takes 1,453,348 annual burden hours.

If additional information is required please contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Suite 3E.405B, Washington, DC 20530.

Dated: August 31, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–21297 Filed 9–2–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1190–NEW]

Agency Information Collection Activities; Proposed eCollection; eComments Requested; Approval of a New Collection; Assessing Potential Benefits of Accessible Web Content for Individuals Who Are Blind

AGENCY: Civil Rights Division, Department of Justice.

ACTION: 30-day notice.

SUMMARY: The Department of Justice (DOJ), Civil Rights Division, Disability Rights Section, will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). This proposed information collection was previously published in the **Federal Register** on June 30, 2016 at 81 FR 43249, on July 1, 2016, allowing for a 60 day public comment period.

DATES: Comments are encouraged and will be accepted for an additional 30 days until October 6, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments (especially on the estimated public burden or associated response time), suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Rebecca B. Bond, Chief, Disability Rights Section, Civil Rights Division, by any one of the following methods: By email at *DRS.PRA@usdoj.gov;* by regular U.S. mail at Disability Rights Section, Civil Rights Division, U.S. Department of Justice, P.O. Box 2885, Fairfax, VA 22031–0885; by overnight mail, courier, or hand delivery at Disability Rights Section, Civil Rights Division, U.S. Department of Justice, 1425 New York Avenue NW., Suite 4039, Washington, DC 20005; or by phone at (800) 514–0301 (voice) or (800) 514–0383 (TTY) (the DRS Information Line). Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* New information collection.

2. *The Title of the Form/Collection:* Assessing Potential Benefits of Accessible Web Content for Individuals Who Are Blind.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form Number: None.

Component: The applicable component within the Department of Justice is the Disability Rights Section in the Civil Rights Division.

4. *Affected public who will be asked to respond, as well as a brief abstract:*

Affected public (Primary): Individuals who are blind.

Affected Public (Other): None.

Abstract: DOJ's Civil Rights Division, Disability Rights Section, is requesting PRA approval of a new information collection to assess potential benefits of accessible Web content to individuals who are blind and to inform future rulemaking under the Americans with Disabilities Act. DOJ proposes to have respondents who are blind interact with Web content that has high accessibility and low accessibility to assess any time savings that people who are blind experience when interacting with accessible Web content. The collection will also request additional information regarding challenges, if any, experienced by respondents while interacting with inaccessible Web content.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 30 respondents will participate at three hours per respondent. All of the respondents will fully complete the collection.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated public burden associated with this collection is 90 hours. It is estimated that respondents will take an average of three hours to complete the process. The burden hours for collecting respondent data sum to 90 hours (30 respondents × 3 hours = 90 hours).

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: August 31, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–21298 Filed 9–2–16; 8:45 am]

BILLING CODE 4410–13–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OMB Number 1121–0184]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of Currently Approved Collection: 2017 School Crime Supplement (SCS) to the National Crime Victimization Survey (NCVS)

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** at 81 FR 42727, on June 30, 2016, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until October 6, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Rachel Morgan, Statistician, Bureau of Justice Statistics, 810 Seventh Street NW., Washington, DC 20531 (email: *Rachel.Morgan@usdoj.gov;* telephone: 202–616–1707). Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20530 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the

proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

(1). *Type of Information Collection:* Revision of currently approved collection.

(2). *Title of the Form/Collection:* School Crime Supplement to the National Crime Victimization Survey.

(3). *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* The form number for the questionnaire is SCS–1. The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

(4). *Affected public who will be asked or required to respond, as well as a brief abstract:* The survey will be administered to persons ages 12 to 18 in NCVS sampled households in the United States. The SCS collects, analyzes, publishes, and disseminates statistics on the students' victimization, perceptions of school environment, and safety at school.

(5). *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimate of the total number of respondents is 8,889 persons ages 12 to 18. Of the 8,889 SCS respondents, 86% or 7,645 will complete the long SCS interview (entire SCS questionnaire) which will take an estimated 15 minutes to complete. The remaining 14% or 1,244 SCS respondents will complete the short interview (*i.e.* will be screened out for not being in school), which will take an estimated 3 minutes to complete. Respondents will be asked to respond to this survey only once during the six month period. The burden estimates are based on data from the prior administration of the SCS.

(6). *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 1,973 total burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: August 31, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–21299 Filed 9–2–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request for Nonmonetary Determination Activity Report

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, "Nonmonetary Determination Activity Report." This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.*

DATES: Consideration will be given to all written comments received by November 7, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free by contacting Ed Medlin by telephone at (202)–693–3259, TTY 1–877–889–5627, (these are not toll-free numbers) or by email at *medlin.edward@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance; 200 Constitution Avenue NW., Washington, DC, 20210; by email at *medlin.edward@dol.gov;* or by fax (202) 693–3975.

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The ETA Nonmonetary Determination Activity Report, contains state data on the number and types of issues that are adjudicated when unemployment insurance (UI) claims are filed. It also has data on the number of disqualifications that are issued for reasons associated with a claimant's separation from employment and reasons related to a claimant's continuing eligibility for benefits. These data are used by the Office of Unemployment Insurance (OUI) to determine workload counts for allocation of administrative funds, to analyze the ratio of disqualifications to determinations, and to examine and evaluate the program effect of nonmonetary activities. The Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)] authorizes this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention Nonmonetary Determination Activity Report, OMB control number 1205–0150.

Submitted comments will also be a matter of public record for this ICR and posted on the Internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

The DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: DOL–ETA.

Type of Review: Extension without changes.

Title of Collection: Nonmonetary Determination Activity Report.

Form: ETA 207.

OMB Control Number: 1205–0150.

Affected Public: State Workforce Agencies.

Estimated Number of Respondents: 53.

Frequency: Quarterly.

Total Estimated Annual Responses: 636.

Estimated Average Time per Response: 4 hours per response.

Estimated Total Annual Burden Hours: 2,544 hours.

Total Estimated Annual Other Cost Burden: $0.

Portia Wu,

Assistant Secretary for Employment and Training Administration.

[FR Doc. 2016–21318 Filed 9–2–16; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comments Request for the Benefits Timeliness and Quality (BTQ) Review System

ACTION: Notice.

SUMMARY: The Department of Labor (DOL), Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, "Benefits Timeliness and Quality Review System." This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.*

DATES: Consideration will be given to all written comments received by November 7, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documents; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free by contacting Edward Medlin by telephone (202–693–3259) (this is not a toll-free number) or by email at *medlin.edward@dol.gov.*

Submit written comments about, or requests a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Room S–4524, 200 Constitution Avenue NW., Washington, DC 20210; or by email at *medlin.edward@dol.gov;* or by fax 202–693–3975.

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The information for ETA 9057 has been revised to adjust the number of small and large states to reflect the most recent data. This category is dependent upon the number of decisions the states issued during the prior calendar year, and varies from year to year. The ETA 9054 Report has been revised to correct a typographical error in Section A. The 3rd time lapse category reads 45–60 (days), but should read 46–60 (days). In addition, the information for ETA 9056 has also been revised and updated to reflect the most recent data. Similar to ETA 9057, ETA 9056 is dependent on the number of nonmonetary determinations reported in the prior calendar year, and varies from year to year.

The Secretary of Labor, under the Social Security Act, Title III, Section 302 (42 U.S.C. 502), funds the necessary cost of proper and efficient administration of each state UI law. The BTQ program collects information and analyzes data. The BTQ data measure the timeliness and quality of states' administrative actions and administrative decisions related to UI benefit payments.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention Benefits Timeliness and Quality Review System, OMB control number 1205–0359.

Submitted comments will also be a matter of public record for this ICR and posted on the Internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

The DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or

other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–ETA.

Type of Review: Revision.

Title of Collection: Benefits Timeliness and Quality Review System.

Form(s): ETA–9050, ETA–9051, ETA–9052, ETA–9054, ETA–9055, ETA–9056, ETA–9057.

OMB Control Number: 1205–0359.

Affected Public: State Workforce Agencies.

Estimated Number of Respondents: 53 state agencies.

Frequency: Monthly and Quarterly.

Total Estimated Annual Responses: 29,196.

Estimated Average Time per Response: 80.5 minutes.

Estimated Total Annual Burden Hours: 38,132 hours.

Total Estimated Annual Other Cost Burden: $0.

Portia Wu,

Assistant Secretary for Employment and Training Administration.

[FR Doc. 2016–21319 Filed 9–2–16; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Authorization Request Forms/Certification/Letter of Medical Necessity

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Office of Workers' Compensation Programs (OWCP) sponsored information collection request (ICR) proposal titled, "Authorization Request Forms/Certification/Letter of Medical Necessity," to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before October 6, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201606-1240-003* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks PRA authority for the Authorization Request Forms/Certification/Letter of Medical Necessity information collection consisting of Forms CA–26 (Authorization Request Form and Certification/Letter of Medical Necessity for Compounded Drugs) and CA–27 (Authorization Request Form and Certification/Letter of Medical Necessity for Opioid Medications). The Federal Employee's Compensation Act (FECA) provides that the OWCP furnish to a Federal employee who is injured while in the performance of duty the services, appliances, and supplies prescribed or recommended by a qualified physician that the OWCP considers likely to cure, give relief, reduce the degree or the period of disability, or aid in lessening the amount of the monthly compensation. *See* 5 U.S.C. 8103. Forms CA–26 and CA–27 require an injured worker's treating physician to answer questions about the prescribed opioids and/or compounded drugs and certify they are medically necessary to treat the work-related injury. Responses to the questions are intended to ensure treating physicians have considered non-opioid and non-compounded drug alternatives and are only prescribing the most cost effective and medically necessary drugs. The forms will also permit the OWCP more easily to track the volume, type, and characteristics of opioids and compounded drugs authorized by the FECA program. The forms will serve as a means for injured workers to continue receiving opioids and compounded drugs only where medically necessary and simultaneously give the OWCP greater oversight in monitoring their appropriate use and gather additional data about their use. FECA section 36(a)(2) authorizes this information collection. *See* 5 U.S.C. 8124(a)(2).

This proposed information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. For additional information, see the related notice published in the **Federal Register** on June 22, 2016 (81 FR 40721).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB ICR Reference Number 201606–1240–003. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–OWCP.

Title of Collection: Authorization Request Forms/Certification/Letter of Medical Necessity.

OMB ICR Reference Number: 2016006–1240–003.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 86,000.

Total Estimated Number of Responses: 71,275.

Total Estimated Annual Time Burden: 43,000 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: September 1, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–21451 Filed 9–2–16; 8:45 am]

BILLING CODE 4510–CH–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Report on Occupational Employment and Wages

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Bureau of Labor Statistics (BLS) sponsored information collection request (ICR) revision titled, "Report on Occupational Employment and Wages," to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before October 6, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201606-1220-002* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–BLS, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks approval under the PRA for revisions to the Report on Occupational Employment and Wages information collection. The Occupational Employment Statistics (OES) survey is a Federal/State establishment survey of wage and salary workers designed to produce data on current detailed occupational employment and wages for each Metropolitan Statistical Area and Metropolitan Division as well as by detailed industry classification. OES survey data assists in the development of employment and training programs established by the Perkins Vocational Education Act of 1998. This ICR has been classified as a revision, because its approval as submitted would update collection materials, eliminate industry-specific long forms for larger establishments, test asking smaller employers to submit electronically as a primary option, and test a new short write-in form that contains variable information targeted to specific establishments. The Wagner-Peyser Act authorizes this information collection. *See* 29 U.S.C. 49l–2.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1220–0042. The current approval is scheduled to expire on October 31, 2016; however, the DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on April 22, 2016 (81 FR 23753).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1220–0042. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: DOL–BLS.

Title of Collection: Report on Occupational Employment and Wages.

OMB Control Number: 1220–0042.

Affected Public: Federal Government; State, Local, and Tribal Governments; and Private Sector—businesses or other for-profits, not-for-profit institutions.

Total Estimated Number of Respondents: 297,521.

Total Estimated Number of Responses: 297,521.

Total Estimated Annual Time Burden: 148,760 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: August 30, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–21303 Filed 9–2–16; 8:45 am]

BILLING CODE 4510–24–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16–063)]

NASA Advisory Council; Science Committee; Ad Hoc Task Force on Big Data; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Ad Hoc Big Data Task Force. This Task Force reports to the NASA Advisory Council's Science Committee. The meeting will be held for the purpose of soliciting and discussing, from the scientific community and other persons, scientific and technical information relevant to big data.

DATES: Wednesday, September 28, 2016, 9:00 a.m.–2:30 p.m., Thursday, September 29, 2016, 9:00 a.m.–2:30 p.m., and Friday, September 30, 2016, 9:00 a.m.–5:00 p.m., Local Time.

ADDRESSES: NASA Ames Conference Center, 200 Bailey Road, Building 152, Rm 116/117, Mountain View, CA 94043.

FOR FURTHER INFORMATION CONTACT: Ms. Ann Delo, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–0750, fax (202) 358–2779, or *ann.b.delo@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. The meeting will also be available telephonically and by WebEx. You must use a touch tone phone to participate in this meeting. Any interested person may call the USA toll free conference call number 877–601–6603 or toll number 1–517–319–9533, passcode 4718658, to participate in this meeting by telephone, for all three days. The WebEx link is *https://nasa.webex.com/;* the meeting number is 990 210 984 and the password is BDTFmtg#3 (case sensitive) for all three days. The agenda for the meeting includes the following topics:

—NASA's Science Data Cyber-Infrastructure

—Access to NASA Science Mission Data Repositories

—Big Data Best Practices in Government, Academia and Industry

—Federal Big Data Initiatives

—Resources and Concerns Specific to Big Data at NASA Ames Research Center

Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID to Security before access to the NASA Ames Research Park where the NASA Ames Conference Center is located. Due to the Real ID Act, any attendees with drivers licenses issued from non-compliant states must present a second form of ID. [Federal employee badge; passport; active military identification card; enhanced driver's license; U.S. Coast Guard Merchant Mariner card; Native American tribal document; school identification accompanied by an item from LIST C (documents that establish employment authorization) from the "List of the Acceptable Documents" on Form I–9]. Non-compliant states are: American Samoa, Minnesota, Missouri and Washington. Foreign nationals attending this meeting will be required to provide a copy of their passport and visa in addition to providing the following information no less than 10 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; passport information (number, country, telephone); visa information (number, type, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee. To expedite admittance, U.S. citizens and Permanent Residents (green card holders) can provide full name and citizenship status 3 working days in advance to International Visits Office, via email at *arc-dl-ivc@mail.nasa.gov* or by fax at (650) 604–5435. It is imperative that the meeting be held on these dates to the scheduling priorities of the key participants.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2016–21271 Filed 9–2–16; 8:45 am]

BILLING CODE 7510–13–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–9068; NRC–2008–0391]

Lost Creek *In Situ* Uranium Recovery Project; Underground Injection Control Class V Wells

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering a license amendment request for Source Material License: SUA–1598, for the Lost Creek *In Situ* Uranium Recovery (ISR) Project located in Sweetwater County, Wyoming. The NRC staff is issuing an environmental assessment (EA) and finding of no significant impact (FONSI) associated with the proposed action.

DATES: The EA and FONSI referenced in this document are available September 6, 2016.

ADDRESSES: Please refer to Docket ID NRC–2008–0391, when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0391. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; or via email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at: *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at: 1–800–397–4209, 301–415–4737, or via email to: *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Kellee Jamerson, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7408, email: *Kellee.Jamerson@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering issuance of a license amendment for Source Materials License SUA–1598 for the Lost Creek ISR Project located in Sweetwater County, Wyoming (ADAMS Accession No. ML15076A380). The licensee, Lost Creek ISR, LLC (LCI), proposes by this request to inject treated wastewater into Underground Injection Control (UIC) Class V disposal wells at the Lost Creek ISR Project site.

The NRC staff has prepared a final EA as part of its review of this proposed license amendment in accordance with the requirements in part 51 of title 10 of the *Code of Federal Regulations* (10 CFR). Based on the final EA, the NRC staff has determined that a FONSI is appropriate. The NRC is also conducting a safety evaluation of the proposed license amendment pursuant to 10 CFR part 20, "Standards for Protection Against Radiation," and 10 CFR part 40, "Domestic Licensing of Source Material," and the results will be documented in a separate Safety Evaluation Report (SER). If LCI's request is approved, the NRC will issue the license amendment following publication of this final EA and FONSI and completion of the SER.

II. Environmental Assessment

Description of the Proposed Action

The Lost Creek site uses the ISR process to recover uranium, which involves two primary processes: Mobilization and recovery. First, LCI mixes a solution, known as lixiviant, from native ground water, oxygen, and bicarbonate, and injects the lixiviant through wells drilled into the subsurface uranium orebody. The lixiviant then mobilizes uranium found in the orebody to create a uranium-laden solution that is pumped from the production wells and through pipelines to the central processing plant. In the processing plant, uranium is recovered from the solution through ion exchange systems, and then concentrated, filtered, and dried in preparation for offsite shipment. The dried product is a solid form of mixed uranium oxides and hydroxides known as yellowcake. The lixiviant is again pumped into the orebody to continue the mobilization and recovery process. Uranium mobilization at the Lost Creek site produces excess water, referred to as production bleed, which contains byproduct material. The production bleed and other liquid wastewater is currently disposed of via UIC Class I deep disposal wells in accordance with LCI's NRC license.

If approved, the proposed license amendment would allow LCI to inject treated wastewater into UIC Class V disposal wells at the Lost Creek site. Per the UIC program, Class V wells are defined as wells used to inject non-hazardous fluids underground. The treatment method proposed by LCI consists of the following phases: (1) Ion exchange, (2) filtration, (3) reverse osmosis, (4) sodium hydroxide addition, and (5) radium removal. During the treatment process, wastewater is separated into two streams: (1) A relatively clean fluid [commonly referred to as permeate], in which most of the total dissolved solids, radionuclides, and trace materials in the fluid are removed; and (2) a concentrated fluid, commonly referred to as brine, in which the salts from the fluid are concentrated. The treated permeate would then be pumped directly to the Class V wells for disposal.

Need for the Proposed Action

Under the existing NRC source materials license SUA–1598, liquid effluents generated from operations and aquifer restoration at the Lost Creek ISR site are currently licensed for wastewater disposal via UIC Class I deep disposal wells. The proposed action would allow LCI to also treat wastewater onsite and dispose of the treated liquid effluents using UIC Class V wells. If approved, LCI's use of the UIC Class V wells would allow for decreased ground water consumption and an increased future ground water restoration rate. This is because LCI proposes instead to treat and return to the Battle Spring Formation the ground water currently disposed of in Class I deep disposal wells. Additionally, because of the accompanying option for managing wastewater, the use of Class V wells will significantly shorten the time required for ground water restoration.

Environmental Impacts of the Proposed Action

The NRC has assessed the potential environmental impacts associated with the proposed action of amending materials license SUA–1598, and has documented the results in the final EA (ADAMS Accession No. ML16216A273). In conducting the environmental review, the NRC staff considered information in the license amendment application (ADAMS Accession No. ML15076A380); information in LCI's response to the NRC's request for additional information (ADAMS Accession No. ML15239A726); and comments from the Bureau of Land Management (BLM) and the Wyoming Department of Environmental Quality (WDEQ) (ADAMS Accession No. ML16197A216).

The NRC staff used the Supplemental Environmental Impact Statement (SEIS) prepared for the original license application for the Lost Creek ISR Project as the baseline for its EA. As documented in the EA, specific environmental resource areas are not expected to be impacted by the injection of treated wastewater into UIC Class V wells. Other environmental resource areas were analyzed and the NRC staff concluded that the impacts resulting from the proposed action are small and not significant. Therefore, the NRC concluded that the proposed action will not result in a significant effect on the quality of the human environment.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the proposed action (*i.e.,* the "no-action" alternative). Under the no-action alternative, NRC would not approve LCI's request to amend materials license SUA–1598 to utilize UIC Class V wells for disposal of treated wastewater. The no-action alternative will result in LCI's continued use of UIC Class I deep disposal wells as their only wastewater disposal method. Impacts from the use of the UIC Class I wells were previously assessed by the NRC in its SEIS for the Lost Creek ISR Project (ADAMS Accession No. ML11125A0006).

Agencies and Persons Consulted

On May 9, 2016, the NRC staff consulted with the WDEQ and the BLM, regarding the environmental impact of the proposed action. The federal and state agency officials provided comments on the EA and concurred on the FONSI.

III. Finding of No Significant Impact

Based on its review of the proposed action, in accordance with the requirement in 10 CFR part 51, the NRC has concluded that the proposed action of amending Source Materials License SUA–1598 for the Lost Creek ISR Project located in Sweetwater County, Wyoming, will have no significant impact on the quality of the human environment. Therefore, the NRC has determined, pursuant to 10 CFR 51.31, that preparation of an environmental impact statement is not required for the proposed action and a FONSI is appropriate.

Dated at Rockville, Maryland, this 29th day of August, 2016.

For the U.S. Nuclear Regulatory Commission.

Craig G. Erlanger,

Director, Division of Fuel Cycle Safety, Safeguards, and Environmental Review Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2016–21308 Filed 9–2–16; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–185 and CP2016–266; MC2016–186 and CP2016–267; MC2016–187 and CP2016–268]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing recent Postal Service filings for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* September 8, 2016 (Comment due date applies to all Docket Nos. listed above)

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2016–185 and CP2016–266; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Express & Priority Mail Contract 32 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* August 30, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Katalin K. Clendenin; *Comments Due:* September 8, 2016.

2. *Docket No(s).:* MC2016–186 and CP2016–267; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Express & Priority Mail Contract 33 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* August 30, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Katalin K. Clendenin; *Comments Due:* September 8, 2016.

3. *Docket No(s).:* MC2016–187 and CP2016–268; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Express & Priority Mail Contract 34 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* August 30, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Jennaca D. Upperman; *Comments Due:* September 8, 2016.

This Notice will be published in the **Federal Register**.

Stacy L. Ruble,
Secretary.

[FR Doc. 2016–21322 Filed 9–2–16; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Express and Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* September 6, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 30, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express & Priority Mail Contract 32 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–185, CP2016–266.

Stanley F. Mires,
Attorney, Federal Compliance.

[FR Doc. 2016–21267 Filed 9–2–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express and Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* September 6, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 30, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express & Priority Mail Contract 34 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–187, CP2016–268.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–21265 Filed 9–2–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express and Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* September 6, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 30, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express & Priority Mail Contract 33 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–186, CP2016–267.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–21266 Filed 9–2–16; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78718; File No. SR–OCC–2016–801]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Withdrawal of an Advance Notice Related to the Adoption of an Options Exchange Risk Control Standards Policy

August 30, 2016.

On March 4, 2016, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission''), pursuant to section 806(e)(1) of the Payment, Clearing, and Settlement Supervision Act of 2010 (''Clearing Supervision Act'')[1] and Rule 19b–4(n)(1)(i) under the Securities Exchange Act of 1934,[2] an advance notice proposing to adopt a new Options Exchange Risk Control Standards Policy and revise its Schedule of Fees to impose on clearing members a fee of two cents per cleared options contract (per side) executed on an options exchange that did not demonstrate sufficient risk controls designed to meet the proposed set of principles-based risk control standards. On April 14, 2016, the Commission requested additional information from OCC pursuant to section 806(e)(1)(D) of the Clearing Supervision Act.[3] Notice of the advance notice was published in the **Federal Register** on April 21, 2016.[4] The Commission received one comment letter in response to the advance notice.[5]

On July 14, 2016, OCC filed a withdrawal of its advance notice (SR–OCC–2016–801) from consideration by the Commission. The Commission is hereby publishing notice of the withdrawal.

By the Commission.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–21249 Filed 9–2–16; 8:45 am]

BILLING CODE 8011–01–P

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[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] 12 U.S.C. 5465(e)(1)(D). OCC did not submit a response to the Commission's request for additional information.

[4] *See* Securities Exchange Act Release No. 77628 (April 15, 2016), 81 FR 23536 (April 21, 2016).

[5] *See* Letter from OCC, dated June 13, 2016, to Brent J. Fields, Secretary, Commission.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78728; File No. SR–NYSEArca–2016–63]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change Relating to the Listing and Trading of Shares of BlackRock Government Collateral Pledge Unit Under NYSE Arca Equities Rule 8.600

August 30, 2016.

I. Introduction

On May 19, 2016, NYSE Arca, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the BlackRock Government Collateral Pledge Unit. The proposed rule change was published for comment in the **Federal Register** on June 2, 2016.[3] On July 14, 2016, pursuant to section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] The Commission has received no comments on the proposed rule change. This order institutes proceedings under section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.

II. Exchange's Description of the Proposal

The Exchange proposes to list and trade shares (''Shares'') of the BlackRock Government Collateral Pledge Unit (''Fund'') under NYSE Arca Equities Rule 8.600, which governs the listing and trading of Managed Fund Shares. The Fund is a series of the BlackRock Collateral Trust (''Trust''), a Delaware statutory trust.[7] BlackRock Fund Advisors is the investment advisor for the Fund (''Adviser''). State Street Bank and Trust Company is the administrator, custodian, and transfer agent for the Fund. BlackRock Investments, LLC will be the Fund's distributor. The Exchange represents that the Adviser is not registered as a broker-dealer, but is affiliated with two broker-dealers. According to the Exchange, the Adviser has implemented and will maintain a fire wall with respect to its affiliated broker-dealers regarding access to information concerning the composition of, and changes to, the Fund's portfolio.[8] In the event (a) the Adviser becomes registered as a broker-dealer or newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser becomes registered as a broker-dealer or newly affiliated with a broker-dealer, it will implement a fire wall with respect to its relevant personnel or such broker-dealer affiliate regarding access to information concerning the composition of, and changes to, the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 77941 (May 27, 2016), 81 FR 35425 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 78328, 81 FR 47222 (July 20, 2016). The Commission designated August 31, 2016 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] The Exchange represents that the Trust is registered under the Investment Company Act of 1940 (''1940 Act''). According to the Exchange, on April 7, 2016, the Trust filed with the Commission its registration statement on Form N–1A under the Securities Act of 1933 (''Securities Act'') and the 1940 Act relating to the Fund (File Nos. 333–210648 and 811–23154) (''Registration Statement''). The Exchange also states that the Trust and the Adviser (as defined herein) have obtained certain exemptive relief under the 1940 Act. *See* Investment Company Act Release No. 29571 (January 24, 2011) (File No. 812–13601) (''Exemptive Order''). The Exchange represents that the Fund will be offered in reliance upon the Exemptive Order.

The Exchange has made the following representations and statements in describing the Fund and its investment strategies, including the Fund's portfolio holdings and investment restrictions.[9]

A. Exchange's Description of the Fund's Principal Investments

According to the Exchange, the Fund's investment objective will be to seek to provide as high a level of current income as is consistent with liquidity and minimum volatility of principal. The Fund will seek to achieve its investment objective by investing, under normal circumstances,[10] at least 80% of its net assets in a portfolio of U.S. dollar-denominated short-term government securities and other money market securities eligible for investment by U.S. government money market funds that seek to maintain a stable net asset value (including indirect investments through the "Underlying Funds," as defined below).

Under normal circumstances, the Fund intends to invest a substantial portion of its assets in the following government money market funds (individually, "Underlying Fund," and together, collectively, "Underlying Funds"), which principally invest in short-term U.S. Treasury bills, notes, and other obligations issued or guaranteed as to principal and interest by the U.S. government or its agencies or instrumentalities, and repurchase agreements secured by such obligations or cash:[11] (1) FedFund and T-Fund (each, a series of BlackRock Liquidity Funds); and (2) BlackRock Premier Government Institutional Fund and BlackRock Select Treasury Strategies Institutional Fund (each, a series of Funds For Institutions Series).[12] The Adviser may add, eliminate, or replace any or all Underlying Funds at any time. Any additions to, or replacements for, the Underlying Funds will also be government money market funds with substantially similar investment characteristics as those applicable to the Underlying Funds. The Adviser or its affiliates may advise the Underlying Funds. The Fund generally will allocate and reallocate its assets among the Underlying Funds on a monthly basis on an approximate *pro rata* basis based on the amount of net assets of each Underlying Fund, subject to minimum investment amounts or other constraints on the Underlying Funds.

The Fund and certain Underlying Funds may invest in various types of U.S. government obligations. The Fund and the Underlying Funds may invest in variable and floating rate instruments. The Fund and the Underlying Funds may transact in securities on a when-issued, delayed delivery, or forward commitment basis. The Fund and the Underlying Funds may invest in repurchase agreements that are secured by either obligations issued or guaranteed as to principal and interest by the U.S. government or agencies or instrumentalities, or by cash.

The securities purchased by the Fund will comply with the quality and eligibility requirements of Rule 2a–7 under the 1940 Act. The securities purchased by the Underlying Funds will comply with all requirements of Rule 2a–7 and other rules of the Commission applicable to money market funds that seek to maintain a stable NAV per share. The Fund itself will invest only in money market securities eligible for investment for funds that comply with Rule 2a–7, but will not be subject to other requirements of Rule 2a–7 applicable to money market funds that seek to maintain a stable NAV.

B. Exchange's Description of the Fund's Other Investments

While the Fund, under normal circumstances, will invest at least 80% of its net assets in the securities and financial instruments described above, the Fund may invest its remaining assets in other assets and financial instruments, as described below.

The Fund and the Underlying Funds may invest in certain U.S. government obligations other than those referenced in the Principal Investments section above, namely Treasury receipts where the principal and interest components are traded separately under the Separate Trading of Registered Interest and Principal of Securities (STRIPS) program. The Fund and certain Underlying Funds also may invest in reverse repurchase agreements. In addition, the Fund may invest in the securities of other investment companies (including money market funds) to the extent permitted by law, regulation, exemptive order, or Commission staff guidance.

C. Exchange's Description of the Fund's Investment Restrictions

According to the Exchange, the Fund will be classified as "diversified" pursuant to the diversification standard set forth in section 5(b)(1) of the 1940 Act.

The Fund intends to maintain the required level of diversification and otherwise conduct its operations so as to qualify as a regulated investment company for purposes of the U.S. Internal Revenue Code of 1986, as amended.

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[8] The Exchange further represents that an investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 ("Advisers Act"). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. The Exchange represents that the Adviser and its related personnel are subject to Advisers Act Rule 204A–1. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[9] The Commission notes that additional information regarding the Trust, the Fund, and the Shares, including investment strategies, risks, net asset value ("NAV") calculation, creation and redemption procedures, fees, Fund holdings disclosure policies, distributions, and taxes, among other information, is included in the Notice and the Registration Statement, as applicable. *See* Notice and Registration Statement, *supra* notes 3 and 7, respectively.

[10] The term "under normal circumstances" includes, but is not limited to, the absence of extreme volatility or trading halts in the fixed income securities markets or the financial markets generally; circumstances under which the Fund's investments are made for temporary defensive purposes; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

[11] Each Underlying Fund is a "government money market fund," as defined in Rule 2a–7 under the 1940 Act and seeks to maintain a stable NAV of $1.00. The Fund, however, will not be a money market fund and will not seek to maintain a stable NAV of $1.00.

[12] According to the Exchange, the Underlying Funds invest in securities maturing in 397 days (13 months) or less (with certain exceptions) and their portfolios will have a dollar-weighted average maturity of 60 days or less and a dollar-weighted average life of 120 days or less.

The Fund may invest up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment). Each Underlying Fund may invest up to an aggregate amount of 5% of its net assets in illiquid securities. The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets. Illiquid assets include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.

The Exchange represents that the Fund will not invest in futures, options, swaps, or forward contracts. The Exchange further represents that the Fund's investments will be consistent with the Fund's investment objective and will not be used to enhance leverage. That is, while the Fund will be permitted to borrow as permitted under the 1940 Act, the Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*e.g.,* 2x and 3x) of the Fund's primary broad-based securities benchmark index (as defined in Form N–1A).

III. Proceedings To Determine Whether To Approve or Disapprove SR–NYSEArca–2016–63 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to section 19(b)(2)(B) of the Act[13] to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to section 19(b)(2)(B) of the Act,[14] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change's consistency with section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be "designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade," and "to protect investors and the public interest."[15]

Under the proposal, the NAV for the Fund's Shares would generally be calculated as of 12:00 p.m., Eastern Time, on each day the New York Stock Exchange is open for trading. The cutoff time for the submission of creation and redemption orders for the Shares would also generally be 12:00 p.m., Eastern Time. The Commission notes the proposal does not provide any explanation for the early NAV calculation time and creation and redemption cutoff time. The proposal also does not explain whether the early NAV calculation time and creation and redemption cutoff time would have any impact on the trading of the Shares, including any impact on arbitrage. Accordingly, the Commission seeks commenters' views on the 12:00 p.m. NAV calculation time and creation and redemption cutoff time, and on whether the Exchange's statements relating to the NAV calculation and the creation and redemption process support a determination that the listing and trading of the Shares would be consistent with section 6(b)(5) of the Act, which, among other things, requires that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and to protect investors and the public interest.

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with section 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.[16]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by September 27, 2016. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by October 11, 2016. The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in the Notice,[17] in addition to any other comments they may wish to submit about the proposed rule change.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2016–63 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca-2016–63. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2016–63 and should be submitted on or before September 27, 2016. Rebuttal comments should be submitted by October 11, 2016.

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[13] 15 U.S.C. 78s(b)(2)(B).

[14] *Id.*

[15] 15 U.S.C. 78f(b)(5).

[16] Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[17] *See supra* note 3.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–21252 Filed 9–2–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. SIPA–178; File No. SIPC–2016–02]

Securities Investor Protection Corporation: Order Approving a Proposed Bylaw Change Relating to SIPC Fund Assessments on SIPC Members

August 30, 2016.

On May 2, 2016, the Securities Investors Protection Corporation ("SIPC") filed with the Securities and Exchange Commission ("Commission") a proposed bylaw change pursuant to section 3(e)(1) of the Securities Investor Protection Act of 1970 ("SIPA")[1] relating to assessments on SIPC member broker-dealers.[2] On May 27, 2016, SIPC consented to a 60-day extension of time before the proposed bylaw change takes effect pursuant to section 3(e)(1) of SIPA.[3] Pursuant to section 3(e)(1)(B) of SIPA, the Commission found that the proposed bylaw change involved a matter of such significant public interest that public comment should be obtained.[4] This meant that the Commission could require the proposed bylaw change to be treated under the procedures in section 3(e)(2) of SIPA applicable to a proposed SIPC rule change.[5] Consequently, pursuant to section 3(e)(2)(A) of SIPA,[6] notice requesting comment on the proposed bylaw change was published in the **Federal Register** on June 20, 2016.[7] The Commission received one comment regarding the proposal.[8] This order approves the proposed bylaw change under section 3(e)(2) of SIPA.[9]

I. Description of the Proposed Bylaw Change

A. Background

SIPA requires SIPC, by bylaw, to impose assessments upon its member broker-dealers as, after consultation with self-regulatory organizations, SIPC may deem necessary and appropriate to establish and maintain a broker-dealer liquidation fund administered by SIPC (the "SIPC Fund") from which all expenditures by SIPC are to be made, including funds used to facilitate the liquidation of broker-dealers.[10] Pursuant to this authority, SIPC collects annual assessments from its members.[11] The amount of the annual assessment is prescribed by SIPA and the SIPC bylaws and is a percentage of the member broker-dealer's net operating revenues from its securities business.[12]

Article 6 of the SIPC bylaws ("Article 6") currently provides for an assessment rate of ¼ of one percent until the SIPC Fund reaches $2.5 billion and SIPC determines that the Fund will remain at or above $2.5 billion for at least six months. Once that determination is made, the assessment rate falls to the minimum assessment permitted under SIPA, which is 0.02 percent.[13] Article 6 also provides that the assessment rate is ¼ of one percent if it is reasonably likely that the balance of the Fund will fall below $2.5 billion and remain at less than $2.5 billion for six months or more.

SIPC represented in its proposed bylaw change filing that it continues to examine whether the Fund "target balance" of $2.5 billion is adequate for SIPC to carry out its mission of customer protection, and that it wished to ensure that at a minimum, and to the extent possible, the Fund does not fall below $2.5 billion. SIPC indicated that it believed it was prudent to consider not only the size of the Fund over a six-month period, but also SIPC's actual expenditures and its projected expenditures from the Fund over a longer term. In addition, SIPC stated that the size of the Fund is more likely to stay at or above the target balance if there is a more gradual reduction in assessment rates before the minimum assessment rate is imposed. Finally, SIPC stated that such measures would make less likely sudden changes in the assessment rate while giving SIPC members some relief in the amount of the assessment that they owe.

B. The Proposed Amendments

With these considerations in mind, SIPC proposed to modify Article 6 in two respects. First, SIPC proposed to impose an intermediary assessment rate that would apply when the balance of the SIPC Fund is expected to be $2.5 billion for at least six months but SIPC's unrestricted net assets—a measure of net assets that takes into account the anticipated cost of ongoing customer protection proceedings—are less than $2.5 billion, as reflected in its most recent audited Statement of Financial Position.[14] Secondly, SIPC proposed to

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[18] 17 CFR 200.30–3(a)(57).

[1] 15 U.S.C. 78ccc(e)(1).

[2] *See* letter dated May 2, 2016 from Josephine Wang, Secretary, SIPC, to Brent J. Fields, Secretary, Commission.

[3] 15 U.S.C. 78ccc(e)(1). This section provides that a proposed bylaw change shall take effect thirty days after the date of the filing of a copy thereof with the Commission, or upon such later date as SIPC may designate or such earlier date as the Commission may determine unless: (1) The Commission, by notice to SIPC setting forth the reasons therefor, disapproves such proposed bylaw change as being contrary to the public interest or contrary to the purposes of SIPA; or (2) the Commission finds that such proposed bylaw change involves a matter of such significant public interest that public comment should be obtained, in which case it may, after notifying SIPC in writing of such finding, require that the procedures set forth in section 3(e)(2) of SIPA be followed with respect to such proposed bylaw change, in the same manner as if such proposed bylaw change were a proposed SIPC rule change.

[4] 15 U.S.C. 78ccc(e)(1)(B).

[5] *See* 15 U.S.C. 78ccc(e)(1)(B); 15 U.S.C. 78ccc(e)(2).

[6] 15 U.S.C. 78ccc(e)(2)(A).

[7] *See Securities Investor Protection Corporation; Notice of Filing of Proposed Bylaw Amendment Relating to Assessment of SIPC Members,* Release No. SIPA–177 (June 15, 2016), 81 FR 39986 (June 20, 2016).

[8] *See* email dated June 17, 2016 from Jay Lanstein, Chief Executive Officer, Cantella & Co., Inc., *available at https://www.sec.gov/comments/sipc-2016-02/sipc201602-1.htm.*

[9] *See* 15 U.S.C. 78ccc(e)(2).

[10] 15 U.S.C. 78ddd. SIPC stated that it solicited the views of self-regulatory organizations regarding the proposed bylaw change. *See* email dated July 22, 2016 from Josephine Wang, Secretary, SIPC, to Brent J. Fields, Secretary, Commission.

[11] 15 U.S.C. 78ddd(d)(2)(C).

[12] *See* 15 U.S.C. 78ddd(d); *Bylaws of the Securities Investor Protection Corporation,* Article 6, *available at http://www.sipc.org/about-sipc/statute-and-rules/bylaws.* Net operating revenues from the securities business are gross revenues from the securities business, as defined in section 16(9) of SIPA, 15 U.S.C. 78lll(9), less total interest and dividend expense, but not exceeding total interest and dividend income. *See* Article 6; SIPC Form SIPC–6, *available at http://www.sipc.org/Content/media/filing-forms/SIPC–6–20130830.PDF.*

[13] 15 U.S.C. 78ddd(c)(2).

[14] *See, e.g.,* SIPC, *2015 Annual Report* at 20, *available at http://www.sipc.org/Content/media/annual-reports/2015-annual-report.pdf* (audited

Continued

lengthen the time period with respect to when a change in assessments becomes effective after notice of the change is published.

1. Imposition of an Intermediary Assessment Rate

When large SIPA liquidation proceedings are pending that require sizeable advances by SIPC, the SIPC Fund could remain at or above the $2.5 billion target level for six months, but then fall significantly below that amount as additional advances are made. Under Article 6, once the Fund reaches the $2.5 billion target level and is projected to remain at or above that amount for six months or more, SIPC could change the assessment rate from ¼ of one percent to 0.02 percent. On the other hand, because projected expenditures in pending proceedings could reasonably cause the balance of the SIPC Fund to be less than $2.5 billion for six months or more, SIPC alternatively could require that the assessment rate remain at ¼ of one percent. SIPC proposed to amend Article 6 to provide clarity as to what actions it might take when the Fund reaches the $2.5 billion target level, to maintain the SIPC Fund at or above the target balance of $2.5 billion, and to offer some relief in the amount of the assessment that member broker-dealers must pay while reducing the likelihood of sudden changes in the rates.

Under the proposed bylaw change, when the SIPC Fund reaches $2.5 billion and is projected to be at $2.5 billion for six months or more, SIPC would consider the balance of its unrestricted net assets, as reflected in its most recent audited Statement of Financial Position.[15] Specifically, SIPC could impose an annual assessment rate of 0.15 percent of a member's net operating revenues from the securities business if: (1) The amount of the SIPC Fund were at $2.5 billion or more; (2) SIPC determined that the Fund will remain at or above $2.5 billion for at least six months; but (3) SIPC's unrestricted net assets were less than $2.5 billion, as reflected in its most recent audited Statement of Financial Condition.

2. Amendment of the Effective Date of a Change in the Assessment

SIPC also proposed to amend Article 6 with respect to when a change in assessments becomes effective. Currently, Article 6 provides that a change in assessments is to occur on the first day of the month following the date on which SIPC announces a change in the assessment and continue until SIPC provides otherwise ("Notice Provision"). Under current practice, the SIPC Board of Directors in the ordinary course determines the rate of assessment at its September meeting. The Board's determination is announced shortly thereafter, and is made effective the first day of the following month.

SIPC proposed to amend the Notice Provision in order to give its member broker-dealers earlier notice of the assessment rate for the following year. Under the proposal, an assessment rate would be effective on the first day of the year following the date on which SIPC announces its determination. Consequently, under the current practice where the assessment is determined at a September meeting of the Board, an assessment rate would be effective on January 1 of the new year. However, the proposal recognizes that there may be emergency situations when the need for an assessment rate to become effective is more immediate. In that case, the assessment rate would be effective on the date announced by SIPC provided that the exigency of the circumstances so warrants.

II. Comments Received

The Commission received one comment regarding the proposal.[16] The commenter stated that the SIPC assessment rate "should be lowered as soon as the SIPC fund reaches its target balance, rather than waiting potentially a full year." The commenter also stated that the proposed reductions in the assessment rate should be further reduced and that unless there is "another major crisis" the flat fee assessment should be reinstated. The commenter further stated that since under the proposal SIPC can immediately raise assessments when warranted and SIPC can borrow from the Treasury if necessary, extracting "unnecessary fees" presents a financial burden to customers of firms that pass the assessments to their customers.

On July 22, 2016, SIPC filed with the Commission a response to the comment.[17] With regard to the comment that the assessment rate should be lowered as soon as the SIPC Fund reaches its target balance, SIPC stated that it believes that lowering the assessment rate gradually "balances the financial interests of its members with the need for robust reserves that are vital to SIPC's mission." In addition, SIPC stated that "with a gradual reduction in rates, the Fund is more likely to stay above the current target balance." With regard to the comment that assessments should be further reduced and that SIPC extracts "unnecessary fees," SIPC stated that "in 20 of its 45 years of operation, most recently from 1996 to March 2009, assessments were the minimum allowed by statute, ranging from $25 to $150 annually." SIPC further stated that "even since the financial crisis of 2008, SIPC has assessed its members at only a fraction of the maximum percentage legally permissible." SIPC also stated that "relating its assessment needs to its net assets instead of to the balance of the SIPC Fund, offers a more realistic and accurate starting point for measuring potential future needs." Accordingly, SIPC stated that it "believes it prudent to consider booked liabilities in addition to the size of the Fund in determining the appropriate assessment rate." With regard to the comment that SIPC should reinstate a flat fee assessment, SIPC stated that "absent legislative change, SIPC may no longer assess a 'flat fee' minimum as suggested by the comment" because "SIPA section 78ddd(d)(1)(C) was amended in 2010 to provide for a minimum assessment no greater than 0.02 percent of the gross revenues from the securities business of SIPC members."

III. Commission Findings

Section 3(e)(2)(D) of SIPA provides that the Commission shall approve a proposed rule change if it finds that the proposed rule change is in the public interest and is consistent with the purposes of SIPA.[18] The Commission finds, pursuant to section 3(e)(2)(D) of SIPA, that the proposed bylaw change is in the public interest and consistent with the purposes of SIPA.[19]

The SIPC Fund, which is built from assessments on its members and the interest earned on the Fund, is used for the protection of customers of members liquidated under SIPA to maintain investor confidence in the securities markets.[20] In order to reduce the

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statement of financial position reporting unrestricted net assets of $1,622,910,520).

[15] Among other items included in the calculation of unrestricted net assets is a provision for trustees' estimated costs to complete ongoing customer protection proceedings. *See, e.g.*, SIPC, *2015 Annual Report* at 20.

[16] *See* email dated June 17, 2016 from Jay Lanstein, Chief Executive Officer, Cantella & Co., Inc., *available at https://www.sec.gov/comments/sipc-2016-02/sipc201602-1.htm.*

[17] *See* email dated July 22, 2016 from Josephine Wang, Secretary, SIPC, to Brent J. Fields, Secretary, Commission.

[18] 15 U.S.C. 78ccc(e)(2)(D).

[19] 15 U.S.C. 78ccc(e)(2)(D).

[20] *See, e.g., Securities Investor Protection Corporation; Notice of Filing of Proposed Bylaw Amendment Relating to Assessment of SIPC Members*, Release No. SIPA–177 (June 15, 2016), 81 FR 39986, 39988 (June 20, 2016).

likelihood that the SIPC Fund does not fall below the $2.5 billion target, the Commission believes that, in setting the assessment rate, it is appropriate to consider not only the size of the Fund over a six-month period, but SIPC's actual expenditures and its projected expenditures from the Fund over a longer term. In addition, the Commission believes that the size of the Fund is more likely to remain at or above the target level if there is a more gradual reduction in rates before the minimum assessment rate is imposed. Finally, the Commission believes that the proposed bylaw change would give SIPC members appropriate relief in the amount of assessment that they owe while maintaining the assessment rate at a level that is designed to keep the fund at the target level. Further, the Commission notes that the Fund plays a critical role in protecting customers of failed broker-dealer.

In addition, the Commission believes that the proposed amendment to the Notice Provision will provide SIPC member broker-dealers with earlier notice of the assessment rate for the following year but also allow for more prompt changes to the assessment level when merited in certain emergency situations.

IV. Conclusion

IT IS THEREFORE ORDERED, pursuant to section 3(e)(2) of SIPA, that the proposed bylaw change is approved.[21]

By the Commission.

Dated: August 30, 2016.

Brent J. Fields,

Secretary.

[FR Doc. 2016–21269 Filed 9–2–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32246; 812–14571]

Voya ETF Trust, et al., Notice of Application

August 30, 2016.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the "Act") for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act. The requested order would permit (a) actively-managed series of certain open-end management investment companies ("Funds") to issue shares redeemable in large aggregations only ("Creation Units"); (b) secondary market transactions in Fund shares to occur at negotiated market prices rather than at net asset value ("NAV"); (c) certain Funds to pay redemption proceeds, under certain circumstances, more than seven days after the tender of shares for redemption; (d) certain affiliated persons of a Fund to deposit securities into, and receive securities from, the Fund in connection with the purchase and redemption of Creation Units; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the Funds ("Funds of Funds") to acquire shares of the Funds; and (f) certain Funds ("Feeder Funds") to create and redeem Creation Units in-kind in a master-feeder structure.

APPLICANTS: Voya ETF Trust (the "Trust'), a Delaware statutory trust that will be registered under the Act as an open-end management investment company with multiple series, Voya Investments, LLC, an Arizona limited liability company, and Directed Services, LLC, a Delaware limited liability company (each of Voya Investments, LLC and Directed Services, LLC, an "Initial Adviser"), each registered as an investment adviser under the Investment Advisers Act of 1940, Voya Investments Distributor, LLC (the "Distributor"), an Arizona limited liability company and broker-dealer registered under the Securities Exchange Act of 1934 ("Exchange Act").

FILING DATES: The application was filed on October 27, 2015 and amended on April 1, 2016.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on September 26, 2016, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: Voya Investment Management, 7337 East Doubletree Ranch Road, Suite 100, Scottsdale, Arizona 85258.

FOR FURTHER INFORMATION CONTACT: Laura J. Riegel, Senior Counsel, at (202) 551–3038, or Mary Kay Frech, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Summary of the Application

1. Applicants request an order that would allow Funds to operate as actively-managed exchange traded funds ("ETFs").[1] Fund shares will be purchased and redeemed at their NAV in Creation Units only. All orders to purchase Creation Units and all redemption requests will be placed by or through an "Authorized Participant", which will have signed a participant agreement with the Distributor. Shares will be listed and traded individually on a national securities exchange, where share prices will be based on the current bid/offer market. Certain Funds may operate as Feeder Funds in a master-feeder structure. Any order granting the requested relief would be subject to the terms and conditions stated in the application.

2. Each Fund will consist of a portfolio of securities and other assets and investment positions ("Portfolio Positions"). Each Fund will disclose on its Web site the identities and quantities of the Portfolio Positions that will form the basis for the Fund's calculation of NAV at the end of the day.

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[21] 15 U.S.C. 78ccc(e)(2).

[1] Applicants request that the order apply to the initial Fund, as well as future series of the Trust and other open-end management investment companies or series thereof that currently exist or that may be created in the future (each, included in the term "Fund"), each of which will operate as an actively-managed ETF. Any Fund will (a) be advised by an Initial Adviser or an entity controlling, controlled by, or under common control with such Initial Adviser (each, an "Adviser") and (b) comply with the terms and conditions of the application.

3. Shares will be purchased and redeemed in Creation Units and generally on an in-kind basis. Except where the purchase or redemption will include cash under the limited circumstances specified in the application, purchasers will be required to purchase Creation Units by depositing specified instruments (''Deposit Instruments''), and shareholders redeeming their shares will receive specified instruments (''Redemption Instruments''). The Deposit Instruments and the Redemption Instruments will each correspond pro rata to the positions in the Fund's portfolio (including cash positions) except as specified in the application.

4. Because shares will not be individually redeemable, applicants request an exemption from section 5(a)(1) and section 2(a)(32) of the Act that would permit the Funds to register as open-end management investment companies and issue shares that are redeemable in Creation Units only.

5. Applicants also request an exemption from section 22(d) of the Act and rule 22c–1 under the Act as secondary market trading in shares will take place at negotiated prices, not at a current offering price described in a Fund's prospectus, and not at a price based on NAV. Applicants state that (a) secondary market trading in shares does not involve a Fund as a party and will not result in dilution of an investment in shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants represent that share market prices will be disciplined by arbitrage opportunities, which should prevent shares from trading at a material discount or premium from NAV.

6. With respect to Funds that hold non-U.S. Portfolio Positions and that effect creations and redemptions of Creation Units in kind, applicants request relief from the requirement imposed by section 22(e) in order to allow such Funds to pay redemption proceeds within fifteen calendar days following the tender of Creation Units for redemption. Applicants assert that the requested relief would not be inconsistent with the spirit and intent of section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds.

7. Applicants request an exemption to permit Funds of Funds to acquire Fund shares beyond the limits of section 12(d)(1)(A) of the Act; and the Funds, and any principal underwriter for the Funds, and/or any broker or dealer registered under the Exchange Act, to sell shares to Funds of Funds beyond the limits of section 12(d)(1)(B) of the Act. The application's terms and conditions are designed to, among other things, help prevent any potential (i) undue influence over a Fund through control or voting power, or in connection with certain services, transactions, and underwritings, (ii) excessive layering of fees, and (iii) overly complex fund structures, which are the concerns underlying the limits in sections 12(d)(1)(A) and (B) of the Act.

8. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act to permit persons that are Affiliated Persons, or Second-Tier Affiliates, of the Funds, solely by virtue of certain ownership interests, to effectuate purchases and redemptions in-kind. The deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions of Creation Units will be the same for all purchases and redemptions and Deposit Instruments and Redemption Instruments will be valued in the same manner as those Portfolio Positions currently held by the Funds. Applicants also seek relief from the prohibitions on affiliated transactions in section 17(a) to permit a Fund to sell its shares to and redeem its shares from a Fund of Funds, and to engage in the accompanying in-kind transactions with the Fund of Funds.[2] The purchase of Creation Units by a Fund of Funds directly from a Fund will be accomplished in accordance with the policies of the Fund of Funds and will be based on the NAVs of the Funds.

9. Applicants also request relief to permit a Feeder Fund to acquire shares of another registered investment company managed by the Adviser having substantially the same investment objectives as the Feeder Fund (''Master Fund'') beyond the limitations in section 12(d)(1)(A) and permit the Master Fund, and any principal underwriter for the Master Fund, to sell shares of the Master Fund to the Feeder Fund beyond the limitations in section 12(d)(1)(B).

10. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–21247 Filed 9–2–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78721; File No. SR–NYSEMKT–2016–75]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 9217 To Add a Provision and Related Fines Addressing Trade-Through Violations

August 30, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on August 17, 2016, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is

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[2] The requested relief would apply to direct sales of shares in Creation Units by a Fund to a Fund of Funds and redemptions of those shares. Applicants, moreover, are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an Affiliated Person, or a Second-Tier Affiliate, of a Fund of Funds because an Adviser or an entity controlling, controlled by or under common control with an Adviser provides investment advisory services to that Fund of Funds.

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 9217 to add a provision and related fines addressing trade-through violations. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the filing is to amend Rule 9217 (Violations Appropriate for Disposition Under Rule 9216(b)) to add a provision and related fines addressing trade-throughs. The proposed amendment would correct an oversight in not including trade-throughs when the Exchange adopted Rule 9217 in connection with the Options Order Protection and Locked/Crossed Market Plan (the "Linkage Plan").

When the Linkage Plan was adopted in 2009, the Exchange filed and received approval for conforming rules,[4] including modifications to Rule 476A (Imposition of Fines for Minor Violation(s) of Rules) to provide for certain violations of Rule 990NY, Rule 991NY, and Rule 992NY to be enforced under the Minor Rule Plan ("MRP").[5] However, the Exchange did not adopt a provision as part of the MRP regarding the avoidance of trade-throughs as required by Rule 991NY(a). Thus, when the Exchange adopted Rule 9217, it did not include violations of trade-throughs, which was likely an oversight because the Exchange simply "retain[ed] its currently applicable list of minor rule violations and accompanying fine levels."[6] The Exchange notes that the rules of other options exchanges, including the BOX Options Exchange LLC ("BOX") and Chicago Board Options Exchange ("CBOE"), include as part of their minor rule plans provisions and related fines for trade-through violations.[7]

To address this oversight, and to align with the rules of other options exchanges, the Exchange proposes to amend Rule 9217 to adopt "[f]ailure to comply with the requirements for avoidance of trade-throughs set forth in Rule 991NY(a)" as MRP Violation 35 and to add provision 35 to the Recommended Fine Schedule. As proposed, when an ATP Holder engages in a pattern or practice of trading through better prices available on other exchanges, the Exchange would recommend a 1st Level Fine of $500; a 2nd Level Fine of $1,000; and a 3rd Level Fine of $2,500. The Exchange notes that these fines are consistent with those adopted by competing options exchanges.[8]

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)[9] of the Securities Exchange Act of 1934 (the "Act"), in general, and furthers the objectives of Section 6(b)(5),[10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market and a national market system. The proposed rule change is also consistent with Sections 6(b)(6) and 6(b)(7) of the Act because it would promote the Exchange's ability to appropriately discipline its market participants and provide fair procedures when addressing violations of Exchange rules that are deemed by the Exchange to be minor in nature.[11]

The proposed change would foster cooperation and coordination with persons engaged in facilitating transactions in securities because addressing violations of trade-throughs in Rule 9217 would align Exchange rules with rules of other options exchanges that likewise have trade-throughs as part of their minor rule plans.[12] In addition, the Exchange believes that the proposed rule change would promote the efficient use and reasonable allocation of Exchange resources such that trade-through violations could be dealt with via the MRP allowing the Exchange to devote more time and effort to more serious violations. The proposed change would also strengthen the Exchange's ability to carry out its oversight responsibilities as a self-regulatory organization and reinforce its enforcement functions. Further, the Exchange believes the proposal would provide notice to, and fair procedures for the disciplining of, ATP Holders and persons associated with ATP Holders for violations of trade-throughs and would, in turn, protect investors and the investing public. The proposed changes are non-discriminatory in that they would be applied equally to all ATP Holders in a similar situation. The proposed changes also permit the Exchange to levy progressively larger fines against a repeat offender, in a manner and an amount consistent with those applied for violations on other markets.[13]

In addition, the proposed changes would promote consistency in minor rule violations and respective SRO reporting obligations, resulting in less burdensome and more efficient regulatory compliance for common permit holders.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change would align Exchange rules with rules of other options exchanges and would therefore promote consistency in minor rule violations and respective SRO reporting obligations, resulting in less burdensome and more efficient regulatory compliance and facilitating performance of regulatory functions.[14] The proposed rule change is not intended to address competitive issues, but rather it is designed to provide notice to, and fair procedures for the disciplining of, ATP Holders and persons associated with ATP Holders for violations of trade-throughs.

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[4] *See* Securities Exchange Act Release No. 60520 (August 18, 2009), 74 FR 43176 (August 26, 2009) (SR–NYSEAmex–2009–19).

[5] The Exchange's MRP fosters compliance with applicable rules and also helps to reduce the number and extent of rule violations committed by ATP Holders and associated persons. The prompt imposition of a financial penalty helps to quickly educate and improve the conduct of ATP Holders and associated persons that have engaged in inadvertent or otherwise minor violations of the Exchange's rules. By promptly imposing a meaningful financial penalty for such violations, the MRP focuses on correcting conduct before it gives rise to more serious enforcement action.

[6] *See* Securities Exchange Act Release No. 77241 (February 26, 2016), 81 FR 11311 (March 3, 2016) (SR–NYSEMKT–2016–30). The Exchange is not proposing to amend Rule 476A, which is part of Section 9A, Legacy Disciplinary Rules, because that rule applies "only to a proceeding for which a Charge Memorandum has been filed with the hearing board under Rule 476(d) *prior to April 15, 2016,* until such proceeding is final; otherwise, the Rule 9000 Series shall apply." *See* Rule 476A (emphasis added).

[7] *See, e.g.,* Securities Exchange Act Release Nos. 69259 (March 29, 2013), 78 FR 20706 (April 5, 2013) (SR–BOX–2013–17); 62602 (July 29, 2010) (regarding BOX Rule 12140(13); [sic] 75 FR 47672 (August 6, 2010) (SR–CBOE–2010–69) (regarding [sic] and CBOE Rule 17.50(g)(12)).

[8] *See supra* note 7.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78f(b)(6) and (7).

[12] *See supra* note 7.

[13] *See supra* note 7.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[15] and subparagraph (f)(6) of Rule 19b–4 thereunder.[16]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[17] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposed rule change will become operative on filing. The Exchange stated that the proposed rule change would allow the Exchange to align its rules with those of competing options exchanges, without delay, and would also strengthen the Exchange's ability to carry out its oversight responsibilities as a self-regulatory organization and reinforce its enforcement functions. The Exchange also stated that waiver of the operative delay would promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission designates the proposed rule change to be operative upon filing.[18]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEMKT–2016–75 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2016–75. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2016–75, and should be submitted on or before September 27, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–21256 Filed 9–2–16; 8:45 am]

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[14] *See supra* note 7.

[15] 15 U.S.C. 78s(b)(3)(A)(iii).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78727; File No. SR–NYSEArca–2016–96]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change To Amend NYSE Arca Equities Rule 8.700 and To List and Trade Shares of the Managed Emerging Markets Trust Under Proposed Amended NYSE Arca Equities Rule 8.700

August 30, 2016.

On July 1, 2016, NYSE Arca, Inc. filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend NYSE Arca Equities Rule 8.700 to permit the use of swaps on equity indices, fixed income indices, commodity indices, commodities or interest rates, and to list and trade shares of the Managed Emerging Markets Trust under proposed amended NYSE Arca Equities Rule 8.700. The proposed rule change was published for comment in the **Federal Register** on July 21, 2016.[3] The Commission has received no comments on the proposal.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Section 19(b)(2) of the Act[4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is September 4, 2016. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider this proposed rule change. Accordingly, the Commission, pursuant to section 19(b)(2) of the Act,[5] designates October 19, 2016, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEArca–2016–96).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–21251 Filed 9–2–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78724; File No. SR–OCC–2016–004]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Withdrawal of a Proposed Rule Change Related to the Adoption of an Options Exchange Risk Control Standards Policy

August 30, 2016.

On March 4, 2016, The Options Clearing Corporation ("OCC") filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt a new Options Exchange Risk Control Standards Policy and revise its Schedule of Fees to impose on clearing members a fee of two cents per cleared options contract (per side) executed on an options exchange that did not demonstrate sufficient risk controls designed to meet the proposed set of principles-based risk control standards. The proposed rule change was published for comment in the **Federal Register** on March 18, 2016.[3] On April 27, 2016, the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change.[4] On June 13, 2016, the Commission issued an order instituting proceedings to determine whether to approve or disapprove the proposed rule change.[5] The Commission received eight comment letters on the proposed rule change.[6]

On July 14, 2016, OCC filed a withdrawal of its proposed rule change (SR–OCC–2016–004) from consideration by the Commission. The Commission is hereby publishing notice of the withdrawal.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–21257 Filed 9–2–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32243; 812–14657]

Rational Advisors, Inc. and Strategy Shares; Notice of Application

August 30, 2016.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the "Act") for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act. The requested order would permit (a) index-based series of certain open-end management investment companies ("Funds") to issue shares redeemable in large aggregations only ("Creation Units"); (b) secondary market transactions in Fund shares to occur at negotiated market prices rather than at net asset value ("NAV"); (c) certain Funds to pay redemption proceeds, under certain circumstances, more than seven days after the tender of shares for redemption; (d) certain affiliated persons of a Fund to deposit securities into, and receive securities from, the Fund in connection with the purchase and redemption of Creation Units; and (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the Funds ("Funds of Funds") to acquire shares of the Funds.

APPLICANTS: Strategy Shares (the "Trust"), a Delaware statutory trust registered under the Act as an open-end management investment company with multiple series and Rational Advisors, Inc. ("RAI"), an Ohio corporation and an investment adviser that is registered as an investment adviser under the Investment Advisers Act of 1940.

FILING DATES: The application was filed on June 6, 2016.

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[3] *See* Securities Exchange Act Release No. 78345 (July 15, 2016), 81 FR 47447.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 77358 (March 14, 2016), 81 FR 14921 (March 18, 2016).

[4] *See* Securities Exchange Act Release No. 77720 (April 27, 2016), 81 FR 26609 (May 3, 2016).

[5] *See* Securities Exchange Act Release No. 78056 (June 13, 2016), 81 FR 39732 (June 17, 2016).

[6] *See* Letters from Mark Dehnert, Managing Director, Goldman Sachs & Co., and Kyle Czepiel, Co-Chief Executive Officer, Goldman Sachs Execution & Clearing, L.P., dated March 28, 2016, to Secretary, Commission; Lisa J. Fall, President, BOX Options Exchange, dated April 6, 2016, to Brent J. Fields, Secretary, Commission; James G. Lundy, Associate General Counsel, ABN AMRO Clearing Chicago LLC, dated April 8, 2016, to Brent J. Fields, Secretary, Commission; Ellen Greene, Managing Director, Securities Industry and Financial Markets Association, dated April 12, 2016, to Robert W. Errett, Deputy Secretary, Commission; Michael J. Simon, Secretary and General Counsel, International Securities Exchange, LLC, dated April 20, 2016, to Brent J. Fields, Secretary, Commission; Edward T. Tilly, Chief Executive Officer, Chicago Board Options Exchange, Inc., dated April 20, 2016, to Brent J. Fields, Secretary, Commission; OCC, dated June 13, 2016, to Brent J. Fields, Secretary, Commission; and Lisa J. Fall, President, BOX Options Exchange, dated June 21, 2016, to Brent J. Fields, Secretary, Commission.

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[7] 17 CFR 200.30–3(a)(12).

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on September 26, 2016, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: 36 North New York Avenue, Huntington, NY 11743.

FOR FURTHER INFORMATION CONTACT: Jean E. Minarick, Senior Counsel, at (202) 551–6811 or Daniele Marchesani, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Summary of the Application

1. Applicants request an order that would allow Funds to operate as index exchange traded funds ("ETFs").[1] Fund shares will be purchased and redeemed at their NAV in Creation Units only. All orders to purchase Creation Units and all redemption requests will be placed by or through an "Authorized Participant", which will have signed a participant agreement with a broker-dealer registered under the Securities Exchange Act of 1934 ("Exchange Act") (together with any future distributor, the "Distributor"). Shares will be listed and traded individually on a national securities exchange, where share prices will be based on the current bid/offer market. Any order granting the requested relief would be subject to the terms and conditions stated in the application.

2. Each Fund will hold investment positions selected to correspond generally to the performance of an Underlying Index. In the case of Self-Indexing Funds, an affiliated person, as defined in section 2(a)(3) of the Act ("Affiliated Person"), or an affiliated person of an Affiliated Person ("Second-Tier Affiliate"), of the Trust or a Fund, of the Adviser, of any sub-adviser to or promoter of a Fund, or of the Distributor will compile, create, sponsor or maintain the Underlying Index.[2]

3. Shares will be purchased and redeemed in Creation Units and generally on an in-kind basis. Except where the purchase or redemption will include cash under the limited circumstances specified in the application, purchasers will be required to purchase Creation Units by depositing specified instruments ("Deposit Instruments"), and shareholders redeeming their shares will receive specified instruments ("Redemption Instruments"). The Deposit Instruments and the Redemption Instruments will each correspond pro rata to the positions in the Fund's portfolio (including cash positions) except as specified in the application.

4. Because shares will not be individually redeemable, applicants request an exemption from section 5(a)(1) and section 2(a)(32) of the Act that would permit the Funds to register as open-end management investment companies and issue shares that are redeemable in Creation Units only.

5. Applicants also request an exemption from section 22(d) of the Act and rule 22c-1 under the Act as secondary market trading in shares will take place at negotiated prices, not at a current offering price described in a Fund's prospectus, and not at a price based on NAV. Applicants state that (a) secondary market trading in shares does not involve a Fund as a party and will not result in dilution of an investment in shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants represent that share market prices will be disciplined by arbitrage opportunities, which should prevent shares from trading at a material discount or premium from NAV.

6. With respect to Funds that effect creations and redemptions of Creation Units in kind and that are based on certain Underlying Indexes that include foreign securities, applicants request relief from the requirement imposed by section 22(e) in order to allow such Funds to pay redemption proceeds within fourteen calendar days following the tender of Creation Units for redemption. Applicants assert that the requested relief would not be inconsistent with the spirit and intent of section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds.

7. Applicants request an exemption to permit Funds of Funds to acquire Fund shares beyond the limits of section 12(d)(1)(A) of the Act; and the Funds, and any principal underwriter for the Funds, and/or any broker or dealer registered under the Exchange Act, to sell shares to Funds of Funds beyond the limits of section 12(d)(1)(B) of the Act. The application's terms and conditions are designed to, among other things, help prevent any potential (i) undue influence over a Fund through control or voting power, or in connection with certain services, transactions, and underwritings, (ii) excessive layering of fees, and (iii) overly complex fund structures, which are the concerns underlying the limits in sections 12(d)(1)(A) and (B) of the Act.

8. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act to permit persons that are Affiliated Persons, or Second Tier Affiliates, of the Funds, solely by virtue of certain ownership interests, to effectuate purchases and redemptions in-kind. The deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions of Creation Units will be the same for all purchases and redemptions and Deposit Instruments and Redemption Instruments will be valued in the same manner as those investment positions currently held by the Funds. Applicants also seek relief from the prohibitions on affiliated transactions in section 17(a) to permit a Fund to sell its shares to and redeem its

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[1] Applicants request that the order apply to the BioShares BioThreat Index ETF and any additional series of the Trust, and any other open-end management investment company or series thereof (each, included in the term "Fund"), each of which will operate as an ETF and will track a specified index comprised of domestic or foreign equity and/or fixed income securities (each, an "Underlying Index"). Any Fund will (a) be advised by RAI or an entity controlling, controlled by, or under common control with RAI (each, an "Adviser") and (b) comply with the terms and conditions of the application.

[2] Each Self-Indexing Fund will post on its Web site the identities and quantities of the investment positions that will form the basis for the Fund's calculation of its NAV at the end of the day. Applicants believe that requiring Self-Indexing Funds to maintain full portfolio transparency will help address, together with other protections, conflicts of interest with respect to such Funds.

shares from a Fund of Funds, and to engage in the accompanying in-kind transactions with the Fund of Funds.[3] The purchase of Creation Units by a Fund of Funds directly from a Fund will be accomplished in accordance with the policies of the Fund of Funds and will be based on the NAVs of the Funds.

9. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–21246 Filed 9–2–16; 8:45 am]

BILLING CODE 8011–01–P

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[3] The requested relief would apply to direct sales of shares in Creation Units by a Fund to a Fund of Funds and redemptions of those shares. Applicants, moreover, are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an Affiliated Person, or a Second-Tier Affiliate, of a Fund of Funds because an Adviser or an entity controlling, controlled by or under common control with an Adviser provides investment advisory services to that Fund of Funds.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78720; File No. SR–FICC–2016–003]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change to Describe the Blackout Period Exposure Charge That May Be Imposed on GCF Repo Participants

August 30, 2016.

On July 12, 2016, the Fixed Income Clearing Corporation (“FICC”) filed with the Securities and Exchange Commission (“Commission”) proposed rule change SR–FICC–2016–003 pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)[1] and Rule 19b–4 thereunder.[2] The proposed rule change was published for comment in the **Federal Register** on July 21, 2016.[3] To date, the Commission has not received comments on the proposed rule change.

Section 19(b)(2) of the Act[4] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is September 4, 2016. The Commission is extending this 45-day time period.

In order to provide the Commission with sufficient time to consider the proposed rule change, the Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change. Accordingly, the Commission, pursuant to section 19(b)(2) of the Act,[5] designates October 19, 2016 as the date by which the Commission shall either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File No. SR–FICC–2016–003).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–21255 Filed 9–2–16; 8:45 am]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 34–78347 (July 15, 2016), 81 FR 47466 (July 21, 2016) (SR–FICC–2016–003).

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78710; File No. 601–01]

Euroclear Bank SA/NV; Notice of Filing of Application To Modify an Existing Exemption From Clearing Agency Registration

August 29, 2016

I. Introduction

On May 9, 2016, Euroclear Bank SA/NV (“EB”) filed with the Securities and Exchange Commission (“Commission”) an application on Form CA–1 requesting to modify an existing exemption[1] (“Existing Exemption”) from clearing agency registration (“Modification Application”)[2] pursuant to Section 17A[3] of the Securities Exchange Act of 1934 (“Exchange Act”) and Rule 17Ab2–1 thereunder.[4] Subject to certain limitations and conditions, the Existing Exemption enables EB as operator of the Euroclear System[5] to perform the functions of a clearing agency with respect to transactions involving certain U.S. government securities (“U.S. Government Securities”)[6] for its U.S.

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[1] *See* Self-Regulatory Organizations; Morgan Guaranty Trust Company of New York, Brussels Office, as Operator of the Euroclear System; Order Approving Application for Exemption From Registration as a Clearing Agency, Exchange Act Release No. 39643 (Feb. 11, 1998), 63 FR 8232 (Feb. 18, 1998) (“Original Exemption Order”); and Self-Regulatory Organizations; Morgan Guaranty Trust Company, Brussels Office, as Operator of the Euroclear System and Euroclear Bank, S.A.; Order Approving Application to Modify an Existing Exemption From Clearing Agency Registration, Exchange Act Release No. 43775 (Dec. 28, 2000), 66 FR 819 (Jan. 4, 2001) (“2001 Exemption Modification Order”) (together the Existing Exemption).

[2] The descriptions set forth in this notice regarding the structure and operations of EB have been largely derived from information contained in EB's amended Form CA–1 application and publicly available sources. The redacted Modification Application and non-confidential exhibits thereto are available on the Commission's Web site.

[3] 15 U.S.C. 78q–1.

[4] 17 CFR 240.17Ab2–1.

[5] “Euroclear System” means the securities settlement system that has been operated by EB or its predecessor since 1968 and the assets, means, and rights related to such services. All services performed by EB that relate to securities settlement and custody are part of the Euroclear System. *See* Modification Application, Exhibit S–1 at 1.

[6] As used herein, the term “U.S. Government Securities” has the same meaning as the term

Continued

participants (“U.S. Participants”) [7] without registering as a clearing agency (“U.S. Government Securities Clearing Agency Activities”).[8]

In the Modification Application, EB has requested that the Commission broaden the Existing Exemption to permit EB to perform certain additional clearing agency services (such as certain central securities depository (“CSD”) services [9] and collateral management services) for its U.S. Participants using equity securities issued by U.S. Issuers [10] (“U.S. Equity Securities”) [11] to fulfill certain collateral obligations. Those additional clearing agency services, referred to herein as the “U.S. Equities Clearing Agency Activities,” specifically consist of the following:

(a) The provision of clearing agency services (such as certain CSD services and collateral management services) in relation to U.S. Participants' use and reuse of U.S. Equity Securities issued by U.S. Issuers in support of collateral obligations utilizing the collateral management services provided by EB in relation to any securities or cash account held at EB that is used to receive collateral (“Collateral Accounts”) [12] in connection with the services described in (b) below and in connection with receipt and delivery from other Euroclear System participants that are users of such collateral management services provided by EB; and

(b) solely for the purpose of implementing the services described in (a) above, the provision of certain clearing agency services for U.S. Participants' receipt and delivery of U.S. Equity Securities in relation to collateral management services through accounts held at EB that are linked to EB's account held at DTC.[13]

EB would create the Collateral Accounts for use in the provision of the U.S. Equities Clearing Agency Activities, and for use in connection with a joint venture between Euroclear SA/NV (“ESA”), the parent company of EB, and The Depository Trust and Clearing Corporation (“DTCC”), called DTCC-Euroclear Global Collateral Ltd. (“DEGCL”). As further described herein, DEGCL would provide an inventory management service (“JV–IMS”) to facilitate, among other things, the repositioning and crediting of assets, including U.S. Equity Securities, throughout the EB infrastructure that would be used to provide the collateral management services.

EB requests that it be permitted to provide the U.S. Equities Clearing Agency Activities without registering as a clearing agency and subject to the applicable conditions specified below. In addition, EB requests that it be permitted to continue providing the U.S. Government Securities Clearing Agency Activities without registering as a clearing agency and under substantially the same conditions as those set forth in the Existing Exemption.

The Commission is publishing this notice to solicit comments from interested persons on the Modification Application. The Commission will consider any comments it receives in making its determination whether to approve the Modification Application.

II. Background

A. EB Organization and Legal Framework

EB is a limited liability company organized under the laws of Belgium and also is authorized in Belgium as a Belgian credit institution. EB is an international CSD and a global provider of clearance, settlement, collateral management, and related services. In particular, EB provides its participants with a means of acquiring, holding, transferring, and pledging security entitlements by electronic book-entry on its records outside of the United States, either free of payment or against payment, in multiple currencies.[14] EB is headquartered in Brussels, Belgium, with a secondary office in Braine l'Alleund, Belgium, branch offices in Wanchai, Hong Kong and Krakow, Poland, and a representative office in New York City.[15]

EB is part of a group of companies that serve as market infrastructures by offering clearing agency services to the domestic markets in Belgium, Netherlands, France, England, Ireland, Sweden, and Finland (collectively with EB, the “Euroclear Group”).[16] Entities in the Euroclear Group are subsidiaries of ESA, a Belgian limited liability company.[17] Control and direction of the Euroclear Group strategic decisions are vested in ESA. ESA provides common services to EB and other affiliated companies of the Euroclear Group.[18] ESA maintains intercompany agreements with EB that set forth respective services and obligations.[19]

As previously noted, all services performed by EB that relate to securities settlement and custody are part of the Euroclear System, which is designated as a securities settlement system under the Belgian Settlement Finality Act.[20] According to EB, Belgian law provides for robust asset protection rights for assets deposited in the Euroclear System and for the protection of the holding of assets on the books of EB.[21] Furthermore, EB represents that Belgian

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“eligible U.S. government securities” used in the Existing Exemption, which consists of government securities described in Section 3(a)(42) of the Exchange Act, except that it does not include any (i) foreign-targeted U.S. government or agency securities or (ii) securities issued or guaranteed by the International Bank for Reconstruction and Development (*i.e.*, the World Bank) or any other similar international organization, and that are (i) Fedwire-eligible U.S. government securities, (ii) mortgage-backed pass through securities that are guaranteed by the Government National Mortgage Association (“GNMA”), and (iii) any collateralized mortgage obligation whose underlying securities are Fedwire-eligible U.S. government securities or GNMA guaranteed mortgage-backed pass through securities and which are depository eligible securities. For reference purposes, Fedwire is a large-value transfer system operated by the Board of Governors of the Federal Reserve System that supports the electronic transfer of funds and of book-entry securities. *See* Original Exemption Order, *supra* note 1, at 8239.

[7] As used herein, the term “U.S. Participant” refers to any Euroclear System participant having a U.S. residence, based upon the location of its executive office or principal place of business, including, without limitation, (i) a U.S. bank (as defined by Section 3(a)(6) of the Exchange Act), (ii) a foreign branch of a U.S. bank or U.S.-registered broker-dealer, and (iii) any broker-dealer registered as such with the Commission, even if such broker-dealer does not have a U.S. residence.

[8] *See* Original Exemption Order, *supra* note 1, at 8232.

[9] As used herein, the term “CSD services” has the meaning set forth in 17 CFR 240.17Ad–22(a)(2). The Commission notes that it has proposed to move this definition to 17 CFR 240.17Ad–22(a)(3). *See* Exchange Act Release No. 34–71699 (Mar. 12, 2014), 79 FR 16865, 16970 (Mar. 26, 2014), *corrected at* 79 FR 29507, 29612 (May 22, 2014).

[10] As used herein, the term “U.S. Issuer” refers to an issuer organized or incorporated under the laws of any state of the United States, territory thereof, or the District of Columbia.

[11] As used herein, the term “U.S. Equity Securities” refers to an instrument that represents a direct ownership in a company, such as a stock, share, certificate of interest, or participation in any profit sharing agreement, preorganization certificate of subscription, voting trust certificate or certificate of deposit for an equity security, limited partnership interest, interest in a joint venture or certificate of interest in a business trust. However, the term “U.S. Equity Securities” does not include interests in structured finance vehicles such as limited partnerships, business trusts, or similar arrangements that have no independent operations and are used solely as special purpose financing vehicles. *See* Modification Application, Exhibit S–1 at 2.

[12] *See* Modification Application, Exhibit S–1 at 10–15. The use of the term Collateral Accounts herein includes both IMS Linked Accounts and EB's collateral management services. For a description of the IMS Linked Accounts, see Modification Application, Exhibit S–1 at 10–11.

[13] *See* Modification Application, Exhibit S–1 at 40.

[14] *See* Modification Application, Exhibit S–1 at 3.

[15] *See* Modification Application, Exhibit I–1.

[16] In 2015, the Euroclear Group had assets under custody of €27.5 trillion, turnover equivalent to €674.7 trillion, and a settlement volume of 190.7 million netted transactions. Euroclear Group's collateral management platform, the Collateral Highway, processed collateralized transactions in 2015 for an amount of €1.068 trillion on a daily basis. *See* Modification Application, Exhibit S–1 at 3.

[17] *See* Modification Application, Exhibit A–2.

[18] *See* Modification Application, Exhibit S–1 at 3.

[19] *Id.*

[20] *See* Modification Application, Exhibit K–5 at 22.

[21] *See* Modification Application, Exhibit S–1 at 35.

law and EB's arrangements provide a high degree of certainty with regards to finality of transfers on EB's books, the holding of collateral in accounts, the contractual framework of participants in the Euroclear System, and default procedures.[22]

To utilize the Euroclear System, EB participants enter into a contractual relationship with EB to open and maintain securities and cash accounts at EB.[23] EB participants agree that their rights to assets held in the Euroclear System are defined and governed by Belgian law.[24] EB states that under Belgian law, it is generally the beneficiary of a statutory lien on assets in accounts held at EB to secure any claim it has against EB participants arising in connection with the clearance or the settlement of transactions through, or in connection with, the Euroclear System, including claims resulting from loans or advances.[25]

B. Regulatory Oversight of EB and ESA

EB represents that it is subject to consolidated supervision by the National Bank of Belgium ("NBB") and the Belgian Financial Services Market Authority ("FSMA").[26] EB also represents that NBB supervises ESA, due to its status as an authorized holding company of a regulated credit institution (*i.e.*, EB) and as an institution assimilated to a securities settlement system (*i.e.*, the Euroclear System).[27]

According to EB, the NBB exercises its supervision over EB and ESA on a consolidated basis.[28] Specifically, the NBB has prudential supervision and oversight over EB as a licensed credit institution operating in Belgium. Furthermore, the NBB supervises EB in its role as operator of the Euroclear System and as a recognized CSD. EB states that the NBB is required to ensure: (1) That EB's clearance, settlement, and payment systems operate properly; (2) that those systems are efficient and sound; and (3) that EB meets the obligations applicable to credit institutions under applicable European law, as adopted into Belgian law.[29] EB represents that the NBB has the authority to order EB to limit, suspend, or stop activities if EB does not comply with the regulatory requirements of its various authorizations.[30] EB also states that the NBB assesses EB under the *Principles for Financial Market Infrastructures* ("PFMI") and considers best practices where appropriate.[31]

EB further represents that the FSMA regulates EB for the purposes of compliance with investor protection rules and rules on the operation, integrity, and transparency of the Belgian financial markets.[32] These include requirements relating to conflicts of interest with clients, customer protection in case of insolvencies, and enforcement of conduct requirements.

C. EB's Existing Exemption

The Commission originally granted the Existing Exemption in 1998 to EB's predecessor, Morgan Guaranty Trust Company of New York, Brussels Office ("MGT-Brussels"), as operator of the Euroclear System (the Original Exemption Order).[33] Before EB replaced MGT-Brussels as the operator of the Euroclear System, the Commission approved a modification to the Original Exemption Order to reflect the change in control of the Euroclear System from MGT-Brussels to EB (the 2001 Exemption Modification Order).[34] Under the Existing Exemption, EB may only provide the U.S. Government Securities Clearing Agency Activities to U.S. Participants.[35]

Under the terms of the Existing Exemption, the Commission placed a limit on the volume of transactions in U.S. Government Securities conducted by U.S. Participants that can be settled through the Euroclear System. Specifically, the average daily volume of U.S. Government Securities settled through the Euroclear System for U.S. Participants may not exceed five percent of the total average daily dollar value of the aggregate volume in U.S. Government Securities.[36] To facilitate the monitoring of compliance with the volume limit and the impact of EB's operations on the U.S. Government Securities market under the Existing Exemption, EB is required to provide the Commission with quarterly reports, calculated on a twelve-month rolling basis, of (i) the average daily volume of transactions in eligible U.S. Government Securities for U.S. Participants that are subject to the volume limit and (ii) the average daily volume of transactions in eligible U.S. Government Securities for all Euroclear System participants, whether or not subject to the volume limit.[37]

EB is also required to notify the Commission regarding material adverse changes in any account maintained in the Euroclear System for U.S. Participants.[38] In addition, EB is required to respond to Commission requests for information regarding any U.S. Participant about whom the Commission has financial solvency concerns, including, for example, a settlement default by a U.S. Participant.[39] The Commission also required the execution of a satisfactory memorandum of understanding with the

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[22] *See* Modification Application, Exhibit S–1 at 35.

[23] *See* Modification Application, Exhibit J.

[24] Specifically, EB represents that EB participants' rights in securities held in the Euroclear System are defined and governed by Belgian Royal Decree No. 62 dated Nov. 10, 1967 on the Deposit of Fungible Financial Instruments and the Settlement of Transactions involving such Instruments or similar Belgian legislation. EB states that the applicable Belgian law is effectively similar to securities entitlements under Revised Article 8 of the Uniform Commercial Code. *See* Modification Application, Exhibit S–1 at 36.

[25] *See* Modification Application, Exhibit E–5 at 34.

[26] *See* Modification Application, Exhibit S–1 at 19.

[27] *See* Modification Application, Exhibit S–1 at 20. According to EB, pursuant to Article 20, § 2 of the Belgian Royal Decree of September 26, 2005, institutions assimilated to a settlement institution may not have shareholdings in commercial companies without the prior approval of the NBB, unless the shareholding is taken in companies whose activities consist, in whole or in part, in the activities which a settlement institution or an institution assimilated thereto may carry out.

[28] *Id.* In addition, EB is submitted to the Regulation 575/2013 of 26 June 2013 on prudential requirements for credit institutions and investment firms (CRR) IV and Regulation 909/2014 of 23 July 2014 on improving securities settlement in the European Union and on central securities depositaries (CSDR). *See* Modification Application, Exhibit K–5 at 16.

[29] *See* Modification Application, Exhibit S–1 at 20.

[30] *Id.*

[31] *See* Modification Application, Exhibit S–1 at 20. The PFMI are standards applicable to financial market infrastructures, such as CSDs and securities settlement systems. Committee on Payment and Settlement Systems (now the Committee on Payment and Market Infrastructure) and Technical Committee of the International Organization of Securities Commissions, Principles for financial market infrastructures (Apr. 16, 2012), *available at http://www.bis.org/publ/cpss101a.pdf.*

[32] *See* Modification Application, Exhibit S–1 at 20–21.

[33] *See supra* note 1.

[34] The change in control of the Euroclear System from MGT-Brussels to EB has been the only modification of the exemption. *See supra* note 1. The 2001 Exemption Modification Order was the last time the Commission modified the Existing Exemption.

[35] *See* Original Exemption Order, *supra* note 1, at 8239.

[36] *See id.* at 8239.

[37] *See* Original Exemption Order, *supra* note 1, at 8240. EB's non-U.S. participants are not subject to any restrictions under the Existing Exemption.

[38] For purposes of the Original Exemption Order, the term "material adverse changes" included (i) the termination of any U.S. Participant; (ii) the liquidation of any securities collateral pledged by a U.S. Participant to secure an extension of credit made through the Euroclear System; (iii) the institution of any proceedings to have a U.S. Participant declared insolvent or bankrupt; or (iv) the disruption or failure in whole or in part in the operations of the Euroclear System either at its regular operating location or at its contingency center. *See* Original Exemption Order, *supra* note 1, at 8240, n.78.

[39] *See* Original Exemption Order, *supra* note 1, at 8240.

Belgian banking and securities regulator (currently the NBB) to facilitate the provision of information by EB to the Commission.[40]

D. EB Collateral Management Services

EB participants are able to utilize various clearance and settlement services through the Euroclear System.[41] Among those services are the EB collateral management services (''EB–CMS''), which provide a framework for exchanging collateral to fulfill bilateral obligations between counterparties.[42] Parties to bilateral arrangements that require the posting of collateral by one party (''Collateral Giver'') in favor of the other party (''Collateral Taker'') may use the EB–CMS to secure credit exposures arising under such bilateral arrangements. The terms of such bilateral arrangements and related collateral needs (including the credit exposure, collateral requirements, and collateral terms) are negotiated and agreed between the parties independently of EB. After such arrangements are agreed, the parties then enter into an agreement with EB to provide the collateral management services.

EB states that its non-U.S. participants use the EB–CMS to meet collateral obligations with a variety of assets, including U.S. Government Securities and U.S. Equity Securities.[43] EB also represents that U.S. Participants currently use the EB–CMS to meet collateral obligations with a wide variety of assets including U.S. Government Securities but not U.S. Equity Securities,[44] as the Existing Exemption prohibits EB from allowing U.S. Participants to hold U.S. Equity Securities in an account held at EB for any purpose. EB states that as part of its contractual documentation with its participants, it prohibits any U.S. Participant from holding U.S. Equity Securities in accounts held at EB for any purpose (''Current Equities Restrictions'').[45] EB represents that automated systems protocols and control procedures are implemented in the Euroclear System to enforce the Current Equities Restrictions. The systems protocols consist of coded validation rules that are part of EB's fully automated and standard processes that run prior to the settlement of any securities movement to or from an account held at EB.[46]

III. EB's Proposed Infrastructure

As introduced earlier and discussed further below, EB has requested that the Commission broaden the Existing Exemption to allow it to provide collateral management services to its U.S. Participants using U.S. Equity Securities. Under the Existing Exemption, EB may already offer the EB–CMS for U.S. Government Securities to both U.S. Participants and non-U.S. participants, but EB may only offer the EB–CMS for U.S. Equity Securities to its non-U.S. participants. EB has made the request to broaden its exempt clearing agency activities for the purpose of assisting its participants' compliance with new regulations described below scheduled to take effect in the near future that will significantly affect the use of collateral. In connection with its request, EB is taking preparatory measures to create the infrastructure to accommodate the U.S. Equities Clearing Agency Activities. For example, as further described below, DEGCL was formed in part to facilitate a U.S. Participant's repositioning of assets in the U.S. Participant's account held at The Depository Trust Company (''DTC'') to create a credit for those assets in the U.S. Participant's Collateral Account held at EB for use in the EB–CMS.

A. New Collateral Regulations

According to the Modification Application, new and enhanced regulatory requirements (''New Collateral Regulations'') are leading counterparties to derivative and financing transactions to seek streamlined margin processing and increased efficiency in the availability and deployment of collateral.[47] These New Collateral Regulations are expected to be implemented in the European Union in the near future.[48] EB states that the regulatory changes include new restrictions on eligible collateral, requiring the use of highly liquid assets, prescribed haircuts, and segregation requirements, as well as a prohibition on rehypothecation for initial margin. EB believes that when fully implemented, the New Collateral Regulations will result in increased capital requirements, mandatory central clearing of more derivative transactions, and new margining rules for bilateral trades, which will increase demand for high quality collateral. EB projects that the requirement for more transactions and exposures to be collateralized globally will result in a significant increase in the number of required collateral movements between market participants, which will have implications for counterparty credit risk, funding and capital charges, and reputational and operational risk.

EB also represents that these regulatory changes include requirements for initial margin for counterparties to certain derivative and financing transactions, as well as a reduction or removal of unsecured thresholds for variation margin. EB expects that these new initial margin requirements will significantly increase the amount of collateral required to support a number of derivative and financing transactions. In addition, EB represents that it is expected that the removal or reduction of unsecured thresholds for variation margin will mean any changes in underlying transaction valuations may trigger increased margin calls, requiring market participants to hold additional collateral available for posting.

EB represents that the New Collateral Regulations therefore are expected to greatly increase the complexity of collateral management and create new competition for collateral.[49] Industry research cited by EB indicates that as these regulatory changes take effect, the volume of required collateral movements will increase and the number of collateral settlement fails and associated costs are likely to rise proportionally.[50]

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[40] *See* 2001 Exemption Modification Order, *supra* note 1, at 821; *see also* Understanding Regarding an Application of Euroclear Bank for an Exemption Under U.S. Federal Securities Laws (January, 30, 2001) *available at https://www.nbb.be/doc/cp/nl/aboutcbfa/mou/pdf/mou_2001-01-30_euroclearbank.pdf.*

[41] *See* Modification Application, Ex. J.

[42] *See* Modification Application, Ex. S–1 at 3.

[43] *See* Modification Application, Exhibit S–1 at 34.

[44] *Id.*

[45] EB's customer contracts provide that: ''Due to restrictions imposed on Euroclear Bank by the United States Securities and Exchange Commission (SE.C.) following SEC Rule 17Ab2–1, equities, ETFs and REITs issued by companies incorporated in a state or territory of the United States can be held in Euroclear Bank by non-US Participants only.'' *See* Modification Application, Exhibit S–1 at 6.

[46] *Id.*

[47] *See* Modification Application, Exhibit S–1 at 6.

[48] *Id.; see also* letter from Gabriel Bernardino, Chair of the Joint Committee of the European Supervisory Authorities to Lord Jonathan Hill, EU Commissioner for Financial Stability, Financial Services and Capital Markets Union European Commission (June 30, 2016) (regarding the delayed adoption of the Joint draft Regulatory Technical Standards on risk mitigation techniques for non-centrally cleared OTC derivatives), *available at https://eiopa.europa.eu/Publications/Joint%20Committee/ESAs%202016%2050%20%28ESAs_joint_letter%20to%20the%20Commission%20on%20delayed%20adoption.pdf.*

[49] EB states that collateral movements will need to be tracked and applied against a growing number and type of credit support documentation, while segregation rules will multiply the number of collateral accounts needed and correspondingly increase the complexity of accurately processing collateral movements across account types, fragmented central clearing and collateral delivery channels. *See* Modification Application, Exhibit S–1 at 7; *see also* Implications of Collateral Settlement Fails: An Industry Perspective on Bilateral OTC Derivatives (Feb. 2016), *available at http://www.imas.org.sg//media/2016/03/03/_Implications_of_Collateral___FINAL.pdf* (''Implications of Collateral Settlement Fails''); Collateral Management in Europe: Searching for Central Intelligence (May 2015), *available at https://www.euroclear.com/dam/Brochures/Euroclear-Collateral-Management-Aite-Paper.pdf;* The

B. DEGCL

DEGCL was formed to help market participants comply with the New Collateral Regulations, and will offer global information, recordkeeping, and processing services for derivatives collateral movements and other types of financing transactions.[51] ESA and DTCC formed the joint venture in 2014, and DEGCL is authorized as a service company by the Financial Conduct Authority ("FCA") in the United Kingdom.[52] EB represents that DEGCL seeks to provide services to its users, including buy-side and sell-side financial institutions, in meeting their risk management and regulatory requirements for the holding and exchange of collateral as required by the New Collateral Regulations.[53] These services will be offered to users located primarily in Europe and the U.S.[54] In particular, DEGCL would provide the JV–IMS to help facilitate the U.S. Equities Clearing Agency Activities.[55]

1. DEGCL JV–IMS

EB represents that the JV–IMS would provide an automated mechanism for an entity that is both a participant of EB and DTC ("JV–IMS User") [56] to receive recommendations on how to reposition assets in the JV–IMS User's account held at DTC, including U.S. Equity Securities, for subsequent crediting of those assets to its Collateral Accounts within the EB–CMS (and for the return of such assets to the JV–IMS User's account held at DTC). To facilitate the JV–IMS, EB will become a participant at DTC, subject to approval by DTC, its standard membership requirements and certain heightened requirements for a non-U.S. entity.[57]

Prior to initial use, a JV–IMS User will set parameters that specify which types of assets in its account held at DTC (and in what amounts) it will make available for the JV–IMS, including any limits or criteria on those assets (such as ratings).[58] The JV–IMS User will then transfer assets that meet the parameters to a sub-account held at DTC that is designated for, and dedicated to, the JV–IMS. (See Step 1 of Chart 1 below.) The JV–IMS will then monitor that information and independently verify that the assets identified by the JV–IMS User meet its own parameters, as well as the EB eligibility requirements (such as an accepted CUSIP number). If so, the JV–IMS will prepare and submit to EB free of payment delivery instructions (which EB will in turn submit to DTC on the JV–IMS User's behalf) to transfer the assets identified by the JV–IMS User in its designated sub-account held at DTC to EB's account held at DTC.[59] (See Step 2 of Chart 1 below.) The JV–IMS will also prepare and submit instructions to EB to credit such transferred assets from EB's account held at DTC to the relevant JV–IMS User's Collateral Accounts. (See Step 2a of Chart 1 below.)

Additionally, the JV–IMS would facilitate the automated return of such assets to the JV–IMS User's account held at DTC when necessary to meet other settlement obligations and for corporate actions by preparing and submitting to EB (for eventual forwarding by EB to DTC) free of payment delivery instructions to transfer such assets from EB's account held at DTC to the relevant JV–IMS User's sub-account held at DTC. Finally, the JV–IMS would report to the JV–IMS User all settlement instructions generated via the JV–IMS, the status of the generated settlement instructions, and other relevant information in regards to such settlement instructions. All of the foregoing would be subject to the DTC rules regarding a link with EB that was approved by the Commission in July 2016.[60]

C. EB Collateral Accounts

After the JV–IMS User's assets are credited to EB's account held at DTC via the JV–IMS processes described above, the assets would then be credited to the Collateral Accounts for the relevant EB participant.[61] As stated above, EB's internal protocols would structure these Collateral Accounts to only allow U.S. Participants: (1) To take receipt of U.S. Equity Securities credited to the account via the JV–IMS process described immediately above; (2) to deliver U.S. Equity Securities out of the Collateral Accounts for mobilization as collateral through the EB–CMS infrastructure and to receive U.S. Equity Securities into the Collateral Accounts mobilized from other participants of the EB–CMS; and (3) to deliver U.S. Equity Securities back to the relevant JV–IMS User's sub-account at DTC. (See Step 3 of Chart 1 below.) EB represents that these transfer and use restrictions on Collateral Accounts would prevent a U.S. Participant's U.S. Equity Securities held in Collateral Accounts from being used for any other purposes in the Euroclear System, such as normal settlement activity, except under certain circumstances involving the default of a Collateral Giver.[62]

Currently, non-U.S. JV–IMS Users may move U.S. Equity Securities from DTC to EB by transferring the securities to an account held at DTC for EB's custodian. If the Modification Application is approved, non-U.S. JV–IMS Users may transfer U.S. Equity Securities to either EB's account held at DTC or an account held at DTC for EB's custodian.

If a JV–IMS User defaults, either a Collateral Taker or a Collateral Giver can notify EB of a default under their bilateral transaction. EB's operations staff would then initiate a process to override the regular controls that govern use of U.S. Equity Securities as collateral and instead would instruct DTC to debit those securities from EB's DTC Account and to credit them to the account held at DTC for EB's custodian, while still being credited to the Collateral Taker's account at EB.[63]

In the Modification Application, EB proposes to amend the Current Equities Restrictions [64] to permit the use by U.S. Participants of U.S. Equity Securities subject to the transfer and use restrictions described above. In all other circumstances, the Current Equities

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Economics of Collateral (Dec. 2013), *available at http://dtcc.com/~/media/Files//WhitePapers/%20Report.ashx.*

[50] *See, e.g.,* Implications of Collateral Settlement Fails, *supra* note 49, at 5.

[51] *See* Modification Application, Exhibit S–1 at 3.

[52] DEGCL's reference number as an authorized service company is 686269. *See* FCA Financial Services Register, *available at https://www.fca.org.uk/register.*

[53] *See* Modification Application, Exhibit S–1 at 7.

[54] *See id.*

[55] *See* Modification Application, Exhibit S–1 at 8.

[56] *See id.*

[57] EB has signed a DTC Participant's Agreement pursuant to which it agreed that the DTC rules shall be a part of the terms and conditions of every contract or transaction that EB may make or have with DTC. *See id.*; *see also* DTC Policy Statements on the Admission of Participants (June 2013).

[58] *See* Modification Application, Exhibit S–1 at 8.

[59] This process is subject to DTC rules governing EB's role in repositioning assets. *See* Self-Regulatory Organizations; The Depository Trust Company; Order Approving Proposed Rule Change To Establish a Link with Euroclear, Exchange Act Release No. 78358 (July 19, 2016), 81 FR 48482 (July 25, 2016) (DTC–2016–004) ("DTC EB Link Rule").

[60] *See id.*

[61] All settlement activity related to the JV–IMS that occurs on the books of DTC is governed exclusively by DTC procedures. All activity related to the use of assets that occurs on the books of EB is governed exclusively by the EB contractual framework. *See* Modification Application, Exhibit S–1 at 9.

[62] *See* Modification Application, Exhibit S–1 at 11.

[63] *Id.*

[64] *See supra* Section II.D.

Restrictions would otherwise remain applicable.

BILLING CODE 8011–01–P

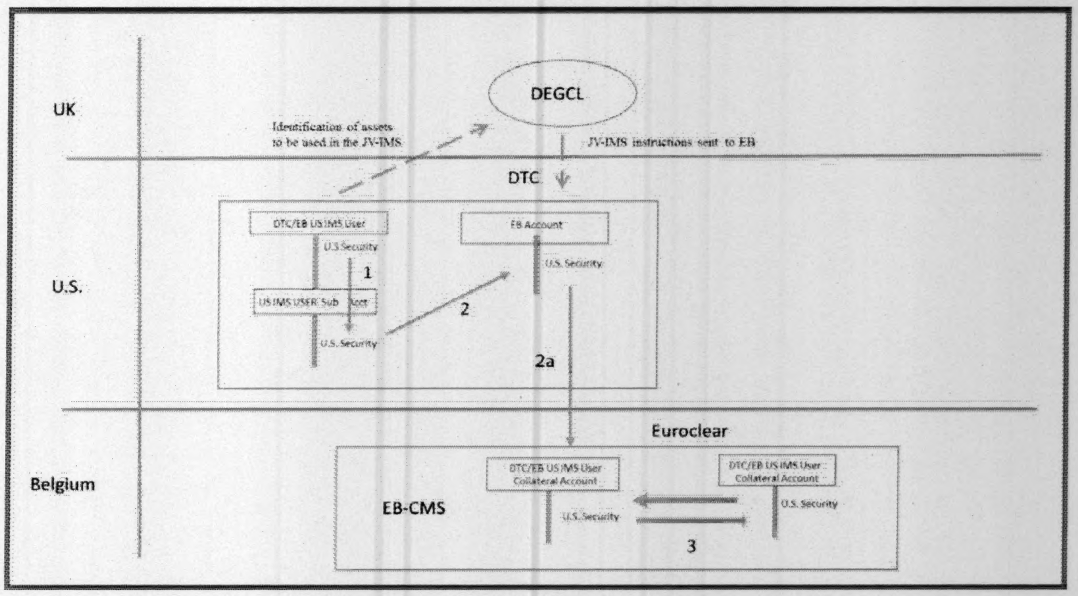
UK
DEGCL
Identification of assets to be used in the JV-IMS
JV-IMS instructions sent to EB
DTC
U.S.
DTC/EB US IMS User
U.S Security
1
US IMS USER Sub Acct
U.S. Security
2
EB Account
U.S. Security
2a
Euroclear
Belgium
EB-CMS
DTC/EB US IMS User Collateral Account
U.S. Security
DTC/EB US IMS User Collateral Account
U.S. Security
3

Chart 1

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IV. The Modification Application

The Modification Application requests that the Commission do the following: (i) Continue the Existing Exemption under substantially similar conditions except as otherwise specified herein, (ii) broaden the Existing Exemption to allow EB to provide the U.S. Equities Clearing Agency Activities under new conditions applicable to those activities, and (iii) apply conditions to EB that are largely harmonized between the U.S. Government Securities Clearing Agency Activities and U.S. Equity Clearing Agency Activities (collectively, the "Clearing Agency Activities").

A. Continue the Existing Exemption on Substantially Similar Conditions Specific to U.S. Government Securities Clearing Agency Activities

EB specifically requests that the Commission continue the Existing Exemption to conduct the U.S. Government Securities Clearing Agency Activities without: (i) Requiring EB to register as a clearing agency with the Commission; (ii) changing the definition of the terms U.S. Government Securities or U.S. Participants, as set forth in the Existing Exemption; or (iii) changing the conditions set forth in the Existing Exemption with regards to the U.S. Government Securities Clearing Agency Activities, listed below:

(a) *Volume Limit.* The average daily volume of transactions in eligible U.S. Government Securities for U.S. Participants processed through EB as operator of the Euroclear System may not exceed five percent of the total average daily dollar value of the aggregate volume in eligible U.S. Government Securities.

(b) *Commission Access to Information regarding U.S. Government Securities Clearing Agency Activities.* EB will continue to provide the Commission with quarterly reports, calculated on a twelve-month rolling basis, of (a) the average daily volume of transactions in eligible U.S. Government Securities for U.S. Participants that are subject to the volume limit as described in Section IV.C.2 of the Original Exemption Order and (b) the average daily volume of transactions in eligible government securities for all Euroclear System participants, whether or not subject to the volume limit as described in Section IV.C.2 of the Original Exemption Order.[65]

EB also requests that the following conditions of the Existing Exemption with regards to the U.S. Government Securities Clearing Agency Activities be replaced and superseded by the corresponding conditions set forth in Part VI.D. below that are applicable to the Clearing Agency Activities:

(a) the obligations in Section IV.C.3 of the Original Exemption Order to provide disclosure documents to the Commission;

(b) the obligations in Section IV.C.3 of the Original Exemption Order to file with the Commission amendments to its application for exemption on Form CA–1; and

(c) the obligations in Section IV.C.3 of the Original Exemption Order to notify the Commission regarding material adverse changes in any account maintained by Euroclear for its U.S. Participants and to respond to a Commission request for information about any U.S. Participant about whom the Commission has financial solvency concerns.[66]

B. Modify the Existing Exemption To Permit EB To Perform U.S. Equities Clearing Agency Activities Subject to Additional Conditions

EB requests that the Commission permit EB to provide, without registering as a clearing agency with the Commission, the U.S. Equities Clearing Agency Activities. As described in the Modification Application, EB's provision of U.S. Equities Clearing Agency Activities would entail activities such as custody and safekeeping,[67] settlement,[68] and asset servicing[69] on behalf of U.S. Participants with respect to U.S. Equity Securities. For example, EB would maintain securities accounts on its books,[70] provide safekeeping of and recordkeeping for those securities accounts,[71] settle instructions by participants,[72] and provide recordkeeping and reporting in real time on the status of settlement to participants.[73] EB would also process corporate actions as part of its asset servicing business for any U.S. Equity Securities that remain in EB's account held at DTC on the record date.[74]

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[65] *See* Modification Application, Exhibit S–1 at 39.

[66] *See id.*

The EB–CMS would be offered to U.S. Participants in support of their obligations under security-based swap transactions, securities lending transactions, and repurchase agreements, among other transactions.[75] The EB–CMS would independently verify that the collateral proposed and provided by the Collateral Giver meets the terms reported by the counterparties for the duration of the collateral obligation.[76] EB would do this by calculating the exchange of value necessary to meet the collateral obligation information entered in by the users of the EB–CMS, including by making value determinations, such as marking to market the value of the collateral based on reference data.[77] Also, EB would generate instructions and communicate the instructions to EB's settlement processing infrastructure to transfer collateral among the Collateral Accounts.[78]

V. Applicable Statutory Standards

A. Section 17A of the Exchange Act

Section 17A of the Exchange Act directs the Commission to facilitate the establishment of (i) a national system for the prompt and accurate clearance and settlement of securities transactions and (ii) linked or coordinated facilities for clearance and settlement of securities transactions.[79] In facilitating the establishment of the national clearance and settlement system, the Commission must have due regard for the public interest, the protection of investors, the safeguarding of securities and funds, and maintenance of fair competition among brokers and dealers, clearing agencies, and transfer agents.[80] Section 17A(b)(1) of the Exchange Act requires all clearing agencies to register with the Commission.[81] It also states that, upon the Commission's motion or upon a clearing agency's application, the Commission may conditionally or unconditionally exempt a clearing agency from any provision of Section 17A of the Exchange Act or the rules or regulations thereunder if the Commission finds that such exemption is consistent with the public interest, the protection of investors, and the purposes of Section 17A of the Exchange Act, including the prompt and accurate clearance and settlement of securities and funds.

The Commission notes that the proposed Clearing Agency Activities would be the only clearing agency activities EB would perform under an exemption order.[82] For example, EB proposes to continue the U.S. Government Securities Clearing Agency Activities on substantially the same basis as under the Existing Exemption. For the purposes of the U.S. Equities Clearing Agency Activities, EB is not proposing to act as a CSD for the issuance of new U.S. Equity Securities, nor is it seeking to facilitate the settlement of purchase and sale transactions in U.S. Equity Securities; its limited role would be to facilitate use by U.S. Participants of U.S. Equity Securities via the EB–CMS. EB also is not proposing to operate as a self-regulatory organization similar to registered clearing agencies or perform other clearing agency functions such as acting as a central counterparty, netting transactions or comparing trade execution information.

The Commission notes that it has previously found an exemption from clearing agency registration to be an appropriate response in instances where an entity has engaged in a limited scope of clearing agency activity. For example, the Commission has previously concluded that entities providing only matching services could obtain an exemption from registration as a clearing agency.[83] Additionally, and similar to the approach taken under the Existing Exemption for EB, the Commission has also previously granted an exemption from registration as a clearing agency to another entity that was performing clearance, settlement, and collateral management services for certain U.S. government securities.[84]

When the Commission approved the Original Exemption Order and the 2001 Exemption Modification Order, it stated that granting either exemptions from portions of Section 17A of the Exchange Act or from registration requires substantial compliance with Section 17A of the Exchange Act and the rules and regulations thereunder based on a review of the standards in place.[85] The Existing Exemption therefore reflected an approach whereby certain determinations were made regarding the then-current rules and structure of EB, as identified in Section 17A(b)(3)(A) through (I) of the Exchange Act. In the Modification Application, EB has represented that it continues to meet the standards previously applied when the Commission approved the Existing Exemption[86] and, for the purposes of its consideration of the Modification Application, the Commission is taking those representations into account.[87] In light of its experience with EB under the Existing Exemption since 1998, as well as its past practice of otherwise exempting from registration certain clearing agencies that perform a limited range of clearing agency services, the Commission preliminarily believes that granting EB an exemption from registration for the Clearing Agency Activities would be appropriate. Therefore, in evaluating the Modification Application, the Commission considers whether exempting EB from clearing agency registration to perform the Clearing Agency Activities satisfies the requirements of an exemption from registration under Section 17A(b)(1) of the Exchange Act, which is consistency with the public interest, the protection of investors and the purposes of Section 17A of the Exchange Act, including the prompt and accurate clearance and settlement of securities and funds.

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[67] *See* Modification Application, Exhibit S–1 at 4.

[68] *See* Modification Application, Exhibit S–1 at 5.

[69] *See* Modification Application, Exhibit S–1 at J–3.

[70] *See* Modification Application, Exhibit S–1 at 2.

[71] *See* Modification Application, Exhibit K–5 at 80–81.

[72] *See* Modification Application, Exhibit K–5 at 76, 83.

[73] *See* Modification Application, Exhibit K–5 at 76.

[74] *See* Modification Application, Exhibit J–3.

[75] *See, e.g.,* Modification Application, Exhibit P–2 (describing necessary revisions to its Operating Procedures related to collateral services, derivatives services, loan services, repurchase services, and securities lending services arising out of the proposed U.S. Equities Clearing Agency Activities).

[76] *See* Modification Application, Exhibit J–3.

[77] *See* Modification Application, Exhibit K–5 at 60 (referencing obtaining the market value of a security. The EB–CMS system does not apply any further haircuts or adjustments once the market value is obtained from third party data providers); *see also* Euroclear plc, Risk Management at Euroclear: Including Pillar 3 Disclosure 2012—Euroclear plc, at 43 (2012) ("Securities for which Euroclear Bank does not obtain external quotations regularly can also be valued according to the price associated with securities transactions in the Euroclear system, or according to theoretical models."), *available at https://www.euroclear.com/dam/Brochures/Pillar3_2012.pdf.*

[78] *See* Modification Application, Exhibit J–3.

[79] *See* 15 U.S.C. 78q–1(a)(2); *see also* Report of the Senate Committee on Banking, Housing & Urban Affairs, S. Rep. No. 94–75, at 4 (1975) (stating that "[t]he Committee believes the banking and security industries must move quickly toward the establishment of a fully integrated national system for the prompt and accurate processing and settlement of securities transactions").

[80] *See* 15 U.S.C. 78q–1(a)(2)(A).

[81] *See* 15 U.S.C. 78q–1(b) and 17 CFR 240.17Ab2–1.

[82] *See* 15 U.S.C. 78c(a)(23). For example, EB will not act as a central counterparty.

[83] *See, e.g.,* Interpretation: Confirmation and Affirmation of Securities Trades; Matching, Exchange Act Release No. 39829 (Apr. 6, 1998), 63 FR 17943 (Apr. 13, 1998); Bloomberg STP LLC; SS&C Technologies, Inc.; Order of the Commission Approving Applications for an Exemption From Registration as a Clearing Agency; Notice, Exchange Act Release No. 34–76514 (Nov. 24, 2015), 80 FR 75388 (Dec. 1, 2015).

[84] *See, e.g.,* Self-Regulatory Organizations; Cedel Bank; Order Approving Application for Exemption From Registration as a Clearing Agency, Exchange Act Release No. 38328 (Feb. 24, 1997), 62 FR 9225 (Feb. 28, 1997).

[85] *See* Original Exemption Order, *supra* note 1, at 8235; 2001 Exemption Modification Order, *supra* note 1, at 820.

[86] *See* Modification Application, Exhibit S–1 at 13.

B. Consistency of the Modification Application With Section 17A of the Exchange Act

The objectives and findings described in Section 17A of the Exchange Act include developing uniform standards and procedures for clearance and settlement, employing new data processing and communication techniques that promote more efficient, effective, and safe clearance and settlement of securities transactions, and reducing the physical movement of securities in the control of a clearing agency or for which a clearing agency has custody. The findings in Section 17A of the Exchange Act also state that the implementation of linked systems and uniform standards would reduce unnecessary costs and increase the protection of investors and persons facilitating transactions by and acting on behalf of investors.

1. Facilitating the Establishment of Linked or Coordinated Facilities for the Settlement of Transactions

In adopting Section 17A of the Exchange Act, Congress found that the linking of settlement facilities and the development of uniform standards and procedures for settlement will reduce unnecessary costs and increase the protection of investors,[88] and directed the Commission to use its authority to facilitate the establishment of linked or coordinated facilities for settlement of transactions in securities.[89] The Commission preliminarily believes that the Modification Application would facilitate the establishment of linked or coordinated facilities for the settlement of securities transactions because, as previously described, the U.S. Equities Clearing Agency Activities are effectuated via the linking of settlement facilities between DTC, a registered clearing agency, and EB, a clearing agency currently exempt from registration. The Commission also preliminarily believes that the linking and coordination of these two settlement facilities will establish uniform standards and procedures that will enable entities that are members of both DTC and EB to position U.S. securities in Europe for use as collateral in a manner that will reduce unnecessary costs and increase the protection of investors.

EB states that, in providing the U.S. Equities Clearing Agency Activities, they are in a unique position as a "neutral, inter-operable, venue-agnostic utility" to source and mobilize collateral across geographical borders and time zones.[90] According to EB, this efficiency would extend to EB's role in both delivering and holding collateral, each of which would otherwise require fragmented, bespoke arrangements among U.S. Participants and their counterparties if conducted on a bilateral basis. The Commission preliminarily believes that the Modification Application could generate certain new efficiencies, such as those that come from using a common platform among multiple participants that can enter into a central, standardized service relationship with EB, rather than entering into multiple relationships with various trading counterparties.[91] This transition to a uniform, unitary set of collateral management procedures through the EB–CMS would also allow U.S. Participants to mobilize a wider range of assets in support of fulfilling the collateral obligations underlying a variety of securities transactions, such as security-based swap transactions. The Commission therefore preliminarily believes that the U.S. Equities Clearing Agency Activities would be consistent with the efficiency objectives of Section 17A of the Exchange Act because they could potentially lead to a lower risk of operational errors that could in turn minimize delivery failures by U.S. Participants (*i.e.,* a failure of a Collateral Giver to deliver or return the required amount and type of collateral to the Collateral Taker on time and in the correct location) by using a uniform, unitary set of collateral management procedures.[92] The Commission also believes that fewer operational errors would help U.S. Participants maintain accurate records, which could help protect investors. The Commission preliminarily believes that these enhancements to collateral delivery mechanisms also could lower the cost of U.S. Participants to manage collateral in support of their transactions with counterparties that are also EB participants.

The Commission notes that, as an alternative to the linked and coordinated approach reflected in the Modification Application, U.S. Participants could instead decide to effectuate settlement and collateral management of certain securities transactions by using the services of various market intermediaries, such as custodians, as well as relying upon internal collateral management and back office functions. The Commission preliminarily believes that the Modification Application could reduce fragmentation of contractual and operational relationships that U.S. Participants must maintain across multiple entities by instead channeling such activity into the standardized procedural framework of the linked and coordinated services provided by DTC and EB through the JV–IMS and the EB–CMS. The Commission also notes that, notwithstanding a U.S. Participant's potential use of the JV–IMS and the EB–CMS, the U.S. Equity Securities would remain immobilized at DTC, and subject to the protections applicable to DTC as a registered clearing agency, such as DTC risk management controls, including its Collateral Monitor and Net Debit Cap.[93] Accordingly, the Commission preliminarily believes that the Modification Application is consistent with the requirements of linked or coordinated facilities, in that it could reduce costs to U.S. Participants and increase the protection of investors and persons facilitating transactions by and acting on behalf of investors.

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[87] The Commission also notes that it has no basis to believe that EB has not operated within and otherwise performed in accordance with the terms and conditions of the Existing Exemption.

[88] *See* 15 U.S.C. 78q–1(a)(1)(D).

[89] *See* 15 U.S.C. 78q–1(a)(2)(A)(ii).

[90] *See* Modification Application, Exhibit K–5 at 7.

[91] *See generally* Rodney Garratt & Peter Zimmerman, Does Central Clearing Reduce Counterparty Risk in Realistic Financial Networks?, Federal Reserve Bank of New York Staff Report No. 717 (Mar. 2015), *available at https://www.newyorkfed.org/medialibrary/media/research/staff_reports/sr717.pdf* (discussing core-periphery networks, and the related assumptions that links to core nodes are desirable, while links to peripheral nodes are not, because agents may prefer to deal with larger players who they are more likely to have existing relationships with; exposures to larger players may be easier to monitor; and economies of scale may mean that these larger players offer more attractive trading terms).

[92] *See* Modification Application, Exhibit S–1 at 16–17.

[93] *See* DTC EB Link Rule, *supra* note 59.

Finally, as discussed below, the Modification Application includes specific reporting conditions on the aggregate movements of U.S. Equity Securities into and out of the EB–CMS, which would not be available in an easily obtainable format if arrangements were conducted on a fragmented bilateral basis, which the Commission preliminarily believes will maximize transparency into these exempted clearing agency activities. The Commission preliminarily believes that the potential for linking and standardizing certain clearing agency services contemplated by the Modification Application could, in addition to yielding risk and operational efficiencies for U.S. Participants, also afford the Commission the ability, through the reporting conditions described below, to observe and more closely monitor clearing agency activity in these areas in a manner that is relatively more efficient than instances where the Commission only has fragmented visibility into a series of bilateral transactions across a series of intermediaries. As the Commission has stated previously, the ability to see the collective activity of various market participants increases transparency by providing information to regulators.[94]

2. Safeguarding Securities and Funds Related to the Settlement of Securities Transactions

Congress also found that the safeguarding of securities and funds related to the settlement of securities transactions is necessary for the protection of investors,[95] and directed the Commission to have due regard for the safeguarding of securities and funds in the use of its authority under Section 17A of the Exchange Act.[96] EB represents that it has appropriate rules, procedures and controls to safeguard the rights of the securities issuers and holders and prevent unauthorized creation or deletion of securities.[97] According to EB, the creation of securities positions is only performed upon receipt of securities to be credited to client accounts. Removal of these securities positions is generally performed upon final maturity or in the context of a corporate event (*e.g.,* an exchange). Both creation and deletion are generally processed without manual intervention at EB upon client instruction and depository confirmation. Movements in client accounts are reported on a daily basis to clients.[98]

EB represents that these procedures and controls are regularly reviewed by EB's internal audit department and by its external auditor. The results of this review are made available to clients and authorities via the yearly ISAE (International Standard on Assurance Engagements) 3402 report, which would be provided to the Commission under the proposed condition in Part IV.C7.[99] In addition, each year, the external auditor reports its findings on EB's internal controls regarding the safekeeping of clients' assets to the Belgian authorities.[100] As previously mentioned, EB is supervised by the NBB, as well as under the investor protection mandate of the Belgian FSMA.

According to EB, it operates under the Euroclear Group's enterprise risk management framework, which includes several features, such as: (i) Risk tolerance levels defined annually by the board of directors of EB, consistent with available capital, and risk tolerance levels set by the management annually with the objective to keep the risk profile low and stable; (ii) implementation of an internal capital adequacy assessment process, expressed in capital requirements over a one-year horizon and an analysis of the potential capital requirements over a five-year time horizon; (iii) comprehensive policies that set out how the internal control system supports repeatability of results; (iv) an active risk register, high-level control objectives and more detailed control objectives to identify, track and mitigate risks; (v) responsibility for risk control at all levels that is clearly assigned, including strong escalation and crises procedures that are regularly tested; (vi) risk management and audit functions that are separate and independent and report directly to the Euroclear Group CEO; (vii) review of quarterly audit and risk reports by the EB and ESA management committees and boards of directors (including the audit committees); and (viii) risk management controls that identify and address six distinct categories of risk (credit risk, liquidity risk, operational risk, market risk, business risk and strategic risk).[101] EB also notes that the U.S. Equity Securities that would be available within the EB–CMS would be transferred only by book-entry on the books of EB and would remain deposited at DTC (either directly or indirectly).[102]

The Commission has previously codified its guidance on safeguarding of funds and securities, requiring registered clearing agencies to develop and maintain plans to assure the safeguarding of securities and funds, the integrity of the automated data processing systems, the recovery of securities, funds, or data under a variety of loss or destruction scenarios, and finally to have business continuity plans that allow for timely recovery of operations and ensure the fulfillment of a registered clearing agency's obligations.[103] The Commission also has previously stated its belief that the immobilization and dematerialization of securities and their transfer by book entry results in reduced costs and risks associated with securities settlements and custody by removing the need to hold and transfer many, if not most, physical certificates.[104] The Commission preliminary believes that the Modification Application is consistent with these expressed goals because transfers will take place via book entry at EB. Accordingly, the Commission preliminarily believes that EB has the ability to safeguard funds and securities consistent with the requirements of the Exchange Act.

3. Prompt and Accurate Settlement of Securities Transactions

As noted above, Congress found that the prompt and accurate clearance and settlement of securities transactions is necessary for the protection of investors,[105] and that inefficient procedures for settlement imposed unnecessary costs on investors.[106] EB states that the Euroclear System is a Model 1 delivery vs. payment ("DVP") system, which means instructions are settled between clients on a trade by trade (gross) basis, with finality of the transfer of securities from the seller to the buyer occurring at the same time as the finality of transfer of funds from the buyer to the seller.[107] EB also states that the Euroclear System controls the availability of the cash and securities before executing instructions (*i.e.,* positioning), so that if the cash and/or the securities are not available, the technical and contractual frameworks would not allow the transaction to be settled.[108] EB offers real-time settlement from around 01:30 to 19:00 Brussels time to cover multiple time zones.[109]

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[94] *See, e.g.,* Standards for Covered Clearing Agencies, Exchange Act Release No. 71699 (Mar. 12, 2014), 79 FR 29508, 29511 (May 22, 2014) (discussing such benefits of intermediation as increases in transparency by making information on market activity and exposures—both prices and quantities—available to regulators and the public).

[95] *See* 15 U.S.C. 78q–1(a)(1)(A).

[96] *See* 15 U.S.C. 78q–1(a)(2)(A).

[97] *See* Modification Application, Exhibit K–5 at 80.

[98] *See* Modification Application, Exhibit K–5 at 81.

[99] *Id.*

[100] *Id.*

[101] *See* Modification Application, Exhibit S–1 at 26–27.

[102] *See* Modification Application, Exhibit S–1 at 37.

[103] *See* 12 CFR 240.17Ad–22(d)(4).

[104] *Id.* at 66253.

[105] *See* 15 U.S.C. 78q–1(a)(1)(A).

[106] *See* 15 U.S.C. 78q–1(a)(1)(B).

The Commission preliminarily believes that approval of the Modification Application would promote the prompt and accurate clearance and settlement of securities transactions and the protection of investors because EB's settlement process is consistent with prior Commission observations regarding DVP systems. In particular, the Commission has previously stated that DVP reduces the risk that a party would lose some or its entire principal because payment is made only if securities are delivered.[110] The Commission also believes that a DVP method reduces the potential that delivery of the security is not appropriately matched with payment for a security. Therefore, the Commission believes the use of a DVP method promotes the clearing agency's ability to facilitate prompt and accurate clearance and settlement.[111]

4. Maintenance of Fair Competition Among Market Participants

Section 17A of the Exchange Act also directs the Commission to have due regard for the maintenance of fair competition in the use of its authority under Section 17A of the Exchange Act.[112] EB states that approving the Modification Application may improve competition among market participants offering collateral management services, but does not expect it to have any impact on the current competitive landscape for provision of settlement of transactions in U.S. Equity Securities for U.S. Participants.[113] EB notes that U.S. Participants already use the EB–CMS today for U.S. Government Securities, but are disadvantaged compared to non-U.S. participants in the range of collateral that they are able to mobilize to meet their collateral obligations in that they are currently unable to use U.S. Equity Securities within the EB–CMS. As a result, EB's proposed service would reduce the disparity between U.S. and non-U.S. participants. EB also states that U.S. Participants currently have, and would continue to have the option of providing U.S. Equity Securities as collateral by using the services of a market intermediary that is not regulated by the Commission as a clearing agency (typically a bank) or by making bilateral collateral management arrangements and undertaking collateral management activities themselves.[114] Accordingly, the Commission preliminarily believes that the Modification Application is consistent with Section 17A of the Exchange Act because the Modification Application should facilitate fair competition between U.S. and non-U.S. participants, and would not prevent U.S. Participants from using other comparable services that may be available.

C. Proposed Conditions

EB represents in its Form CA–1 that it would comply with a series of conditions, as described further below, which are designed to establish an appropriately robust regulatory framework over the limited range of Clearing Agency Activities EB proposes to offer. These conditions are set forth in three sections: (A) Continuation of two existing conditions applicable to the U.S. Government Securities Clearing Agency Activities, (B) operational risk conditions applicable to the Clearing Agency Activities, and (C) additional conditions applicable to the Clearing Agency Activities.

With respect to Section B, the Commission preliminarily believes that the conditions constitute a robust framework of operational conditions to be applied to those EB systems that facilitate the Clearing Agency Activities. Under the Existing Exemption, EB was not subject to the Commission's Automated Review Policy.[115] As a result, EB does not meet the definition of SCI entity as set forth in Rule 1000 of Regulation SCI, and is therefore not subject to the Commission's Regulation Systems Compliance and Integrity ("Regulation SCI").[116] The Commission preliminarily believes that it is appropriate to apply operational conditions that would require EB to have sufficiently resilient systems to support the limited services upon which U.S. Participants may rely.

The proposed conditions in Part VI.C are tailored to the operations of the Clearing Agency Activities and seek to address the same policy concerns that were addressed by Regulation SCI, specifically the reduction of the occurrence of systems issues, the improvement of resiliency of systems, and the enhancement of the Commission's oversight and enforcement of technology infrastructure. The Commission believes that resiliency conditions are warranted because an operational disruption at EB could impact U.S. Participants. The Commission understands that EB would use the same set of collateral management applications and core settlement processing infrastructure housed in the Euroclear System for the U.S. Equities Clearing Agency Activities as it uses for the U.S. Government Securities Clearing Agency Activities, so the operational conditions would apply across both distinct sets of activities.

Several of the proposed conditions in Part VI.D are reformulations of general disclosure and notification conditions that apply generally to EB's operations in performing the U.S. Government Securities Clearing Agency Activities, as previously applied under the Existing Exemption. Specifically, conditions D.3, D.5 and D.7 are taken from the Original Exemption Order and would be applied to the Clearing Agency Activities. Likewise, the conditions would continue to require EB to (i) respond to Commission requests for information concerning financial solvency concerns of U.S. Participants and (ii) file amendments to its application for exemption on Form CA–1 if it makes any material change to the Clearing Agency Activities to allow the Commission to perform ongoing monitoring of any future modified order.

Additionally, the Commission preliminarily believes that the routine provision of certain information by EB would be appropriate to facilitate the monitoring of the impact of EB's expanded, but still limited, Clearing Agency Activities on the national clearance and settlement system. The conditions would expand the reporting conditions as a result. Under the Original Exemption Order, the Commission required EB to provide to the Commission any disclosure documents provided to Euroclear System participants, such as any amendments to the terms and conditions governing the service, any changes to the operating procedures of the Euroclear System, the annual shareholder report, and the annual internal controls report.[117] Under proposed condition D.2, EB would be required to notify the Commission of any material changes to any service agreement between it and any other entity that is performing Clearing Agency Activities. Under proposed condition D.4, EB would provide the Commission an annual report that would describe material changes that do not otherwise necessitate the filing of an amendment of the Form CA–1. The annual report would further require a description of the functioning of EB's monitoring its own compliance and the compliance of third-party service providers with conditions of any modified order. Finally, the annual report would require a description of the management of any conflicts of interest between EB and an affiliated or third-party service provider. The Commission preliminarily believes the notification and annual reporting conditions would facilitate the general monitoring of the Clearing Agency Activities, and in particular, the contractual and operational relationships between EB and ESA, as well as between EB and DTCC. ESA and DTCC, through the Euroclear System and DEGCL, respectively, could play instrumental roles in the EB–CMS, and the Commission preliminarily believes that ongoing updates on these relationships are appropriate to allow the Commission the ability to assess EB's reliance on affiliates to perform clearing agency functions related to the Clearing Agency Activities.

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[107] *See* Modification Application, Exhibit K–5 at 7.

[108] *See* Modification Application, Exhibit K–5 at 83.

[109] *See* Modification Application, Exhibit K–5 at 127.

[110] *See* Clearing Agency Standards, Exchange Act Release No. 68080 (Oct. 22, 2012), 77 FR 66220, 66256 (Nov. 2, 2012).

[111] *Id.*

[112] *See* 15 U.S.C. 78q–1(a)(2)(A).

[113] *See* Modification Application, Exhibit S–1 at 21.

[114] *See* Modification Application, Exhibit S–1 at 22.

[115] *See* Exchange Act Release Nos. 27445 (Nov. 16, 1989), 54 FR 48703 (Nov. 24, 1989), and 29185 (May 9, 1991), 56 FR 22490 (May 15, 1991).

[116] *See* Regulation Systems, Compliance and Integrity, Exchange Act Release No. 73639 (Nov. 19, 2015), 79 FR 72252 (Dec. 5, 2014).

The Commission also preliminarily believes that the new recordkeeping and examination conditions would help the Commission assess EB's compliance with the conditions of any future modified order. Under conditions C.8 and D.5, EB would be required to keep records of documents relating to compliance with the operational conditions and records pertaining to the Clearing Agency Activities covered within the scope of the modified exemption. Under condition D.6, EB would be required to respond to information requests and to allow on-site inspections of facilities, records, and personnel for the purpose of reviewing the Clearing Agency Activities' operations and compliance with the federal securities laws and any future modified order issued by the Commission. The recordkeeping and examination conditions should facilitate periodic review of EB's adherence to the conditions. Finally, under condition D.1, EB would be required to provide annual audited financial statements prepared by competent independent audit personnel, to assist the Commission's monitoring of EB's ongoing condition.

VI. Conditions to Exemption From Clearing Agency Registration

As mentioned above, EB represents in its Form CA–1 that it would comply with all of the conditions described below. EB believes that these conditions are consistent with the public interest, the protection of investors, and the purposes of Section 17A of the Exchange Act.

The following set of conditions, which would replace and supersede all conditions set forth in the Existing Exemption, to read as follows:

A. Continuation of Existing Conditions Applicable to the U.S. Government Securities Clearing Agency Activities

(1) The average daily volume of eligible U.S. Government Securities processed for U.S. Participants through EB as operator of the Euroclear System may not exceed five percent of the total average daily dollar value of the aggregate volume in eligible U.S. Government Securities.

(2) EB will provide the Commission with quarterly reports, calculated on a twelve-month rolling basis, of (a) the average daily volume of transactions in eligible U.S. Government Securities for U.S. Participants that are subject to the volume limit and (b) the average daily volume of transactions in eligible U.S. Government Securities for all Euroclear System participants.

B. Condition Applicable to the U.S. Equities Clearing Agency Activities

EB shall provide to the Commission or its designee quarterly reports, calculated on a twelve-month rolling basis, of (1) the average daily value of U.S. Equity Securities that are held in Collateral Accounts at EB for U.S. Participants and a break-down of the general types of EB collateral agreements in respect of which such value is given as collateral, (2) the average daily value of U.S. Equity Securities that are held in EB's account at DTC relating to inventory management services, and (3) the total value, and a break-down of the general types of EB collateral agreements in respect of which such value is given as collateral, of U.S. Equity Securities that are transferred from Collateral Accounts of U.S. Participants at EB to other Securities Clearance Accounts at EB (other than IMS-Linked Accounts) pursuant to a liquidation of such collateral.

C. Operational Risk Conditions Applicable to Clearing Agency Activities

(1) EB shall demonstrate to the Commission or its designee prior to commencing the U.S. Equities Clearing Agency Activities that EB maintains written policies and procedures applicable to those systems that support or are integrally related to the Clearing Agency Activities (the "Systems") that, on an ongoing basis, are reasonably designed to:

(a) Establish a robust operational risk-management framework applicable to the Systems with appropriate systems, policies, procedures, and controls to identify, monitor, and manage operational risks;

(b) clearly define the roles and responsibilities of EB personnel for addressing operational risk (*e.g.,* identify a senior manager responsible for compliance with the operational conditions applicable to the Systems);

(c) review operational policies, procedures, and controls applicable to the Systems;

(d) audit the Systems, and test the Systems periodically and at implementation of significant changes;

(e) clearly define operational reliability objectives for the Systems;

(f) ensure that the Systems have scalable capacity adequate to handle increasing stress volumes and achieve the Systems service-level objectives;

(g) establish comprehensive physical and information security policies that address all potential vulnerabilities and threats to the Systems;

(h) establish a business continuity plan for the Systems that addresses events posing a significant risk of disrupting the Systems' operations, including events that could cause a wide-scale or major disruption in the provision of the Clearing Agency Activities;

(i) incorporate the use of a secondary site in EB's business continuity plan that is designed to ensure that the Systems can resume operations within two hours following disruptive events; and

(j) regularly test or otherwise validate EB's business continuity plans; and identify, monitor, and manage the risks that key participants, other financial market infrastructures, and service and utility providers might pose to the Systems' operations in relation to the Clearing Agency Activities.

(2) For purposes of condition C.1, such policies and procedures shall be consistent with current information technology industry standards, which

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[117] *See* Original Exemption Order, supra note 1, at 8240.

shall be comprised of information technology practices that are widely available to information technology professionals in the financial sector and issued by a widely recognized organization. EB shall inform the Commission or its designee of the information technology industry standards that EB has chosen to use, affirm that choice on an annual basis, and provide advance notice of the use of different standards as soon as practicable.

(3) EB shall provide the Commission or its designee with an annual update on the status of the items set forth in condition C.1.

(4) EB shall establish, implement, maintain, and enforce written policies and procedures reasonably designed to ensure that the Systems operate on an ongoing basis in a manner that complies with the conditions applicable to the Systems and with EB's rules and governing documents applicable to the Clearing Agency Activities.

(5)(a) Upon EB having a reasonable basis to conclude that a disruption, compliance issue, or intrusion of the Systems that impacts, or is reasonably likely to impact, the Clearing Agency Activities has occurred (a "Systems Event"), EB shall:

(i) Take appropriate corrective action, which shall include, at a minimum, devoting adequate resources to remedy the Systems Event as soon as reasonably practical;

(ii) notify the Commission or its designee of such Systems Event within 24 hours after occurrence;

(iii) until such time as a Systems Event is resolved and EB's investigation of the Systems Event is closed, provide updates pertaining to such Systems Event to the Commission or its designee on a regular basis;

(iv) within 48 hours after the occurrence of a Systems Event or where EB reasonably determines that such deadline cannot be met and so notifies the Commission or its designee, promptly thereafter, submit an interim written notification pertaining to such Systems Event to the Commission or its designee containing: (A) A detailed description of: The relevant discovery and duration times, detection, root cause and remedial actions taken or planned regarding the Systems Event (to the extent known at report time); EB's assessment of the entities (including types of market participants) and EB services affected by the Systems Event; EB's assessment of the impact of the Systems Event on the Participants; and any other pertinent information known by the EB about the Systems Event; and (B) a copy of any information disseminated to EB's U.S. Participants in accordance with EB's notification practices regarding the Systems Event;

(v) within ten business days after the occurrence of a Systems Event, or where EB reasonably determines that such deadline cannot be met and so notifies the Commission or its designee, promptly thereafter, submit a written final report regarding the matters covered in the interim report required under (iii) above to the Commission or its designee; and

(vi) for Systems Events characterized as "Bronze level" events (*i.e.,* a Systems Event in which the incident is clearly understood, almost immediately under control, involves only one business unit and/or entity, and is resolved within a few hours), in lieu of the reporting in (i) through (v) above, provide on a quarterly basis an aggregated list of Bronze level events.

(b) As used herein: (i) A "disruption" means an event in the Systems that disrupts, or significantly degrades, the normal operation of the Systems in relation to the Clearing Agency Activities; (ii) a "compliance issue" means an event at EB that has caused any System to operate in a manner that does not comply with the applicable conditions or EB's rules and governing documents applicable to the Clearing Agency Activities; and (iii) an "intrusion" means any unauthorized entry into the Systems in relation to the Clearing Agency Activities.

(6) EB shall, within 30 calendar days after the end of each quarter, submit to the Commission or its designee a report describing completed, ongoing, and planned material changes to the Systems that support or are related to the Clearing Agency Activities during the prior, current, and subsequent calendar quarters, including the dates or expected dates of commencement and completion. EB shall establish reasonable written criteria for identifying a change to the Systems as material and report such changes in accordance with such criteria.

(7) EB shall provide the Commission or its designee with: (a) Annually, the audited control report made available to EB's Participants prepared in accordance with internationally accepted standards for assurance reports on controls at a service organization (such as the International Standard on Assurance Engagements (ISAE) Standard No. 3402); (b) annually, copies of those portions of any annual control report provided by EB to its primary Belgian regulator that describes controls applicable to the Systems as used to support or in relation to the Clearing Agency Activities; and (c) copies of agendas, reports and presentation materials relating to the capacity, integrity, resiliency, availability, and security or compliance of the Systems that are provided by EB or its primary Belgian regulator to any committee of regulators that implements the memorandum of understanding among regulators of Euroclear Group's CSD entities that provides for the coordinated and common oversight and supervision of the Euroclear Group.

(8) EB shall make, keep, and preserve at least one copy of all documents relating to its compliance with the operational risk conditions; keep all such documents for a period of not less than five years, the first two years in an easily accessible place (which may be located in the European Union); and upon request of the Commission, promptly furnish to the possession of the Commission or its designee copies of any such documents.

D. Additional Conditions Applicable to the Clearing Agency Activities

(1) EB shall provide to the Commission or its designee its annual audited financial statements prepared by competent independent audit personnel.

(2) EB shall notify the Commission or its designee of any material changes to any service agreement between EB and any other entity that is performing Clearing Agency Activities on behalf of EB if such changes are reasonably expected to materially affect the Clearing Agency Activities.

(3) EB will notify the Commission or its designee (a) promptly following termination of any U.S. Participant as a participant in the Euroclear System, (b) promptly following the liquidation by EB of any securities collateral pledged by a U.S. Participant to EB to secure an extension of credit made through the Euroclear System, and (c) promptly following EB becoming aware of the institution of any proceedings to have a U.S. Participant declared insolvent or bankrupt, and will respond to Commission requests for information about any U.S. Participant about whom the Commission has financial solvency concerns, including, for example, a settlement default by a U.S. Participant.

(4) EB shall annually provide to the Commission or its designee a report describing: (a) Material changes to the representations made by EB in support of the approval of this Order that would not otherwise require amendment of EB's application for exemption on Form CA–1 in accordance with these conditions; (b) the functioning of EB's policies and procedures for monitoring its own compliance with the conditions

of this order regarding the Clearing Agency Activities (and the compliance of any affiliated or third-party service provider referred to in condition D.2); and (c) the management by EB of any conflicts of interest of such affiliated or third-party service provider that EB becomes aware have arisen since the prior report with respect to the performance of the Clearing Agency Activities.

(5) EB shall keep records relating to the Clearing Agency Activities regarding settlement details, account details, service agreements, and service notices sent to U.S. Participants pertaining to the operation of the Clearing Agency Activities and retain such records for a period of not less than five years, the first two years in an easily accessible place (which may be located in the European Union).

(6) EB shall respond to and require its service providers to respond to a request from the Commission for additional information relating to the Clearing Agency Activities and provide access to the Commission or its designee to conduct on-site inspections of all facilities (including automated systems and systems environment), records, and personnel related to the Clearing Agency Activities. The request for information shall be made and the inspections shall be conducted solely for the purpose of reviewing the Clearing Agency Activities' operations and compliance with the federal securities laws and the terms and conditions in any order exempting EB from registration as a clearing agency with regard to the Clearing Agency Activities.

(7) EB shall file with the Commission amendments to its application for exemption on Form CA–1 if it makes any material change to the Clearing Agency Activities or any change materially affecting the Clearing Agency Activities as summarized in the relevant exemption order, EB's amended Form CA–1 or in any subsequently filed amendments to its Form CA–1 that would make such previously provided information incomplete or inaccurate.

VII. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed exemption is consistent with the public interest, the protection of investors, and the purposes of Section 17A of the Exchange Act. To the extent possible, commenters are requested to provide empirical data and other factual support for their views. In addition, the Commission seeks comment generally on the following issues:

1. Would the Modification Application, if approved, achieve the underlying policy objectives of the Exchange Act? Why or why not? In particular, please address whether granting an exemption from registration does or does not further the goals of promoting investor protection and the integrity of the securities markets.
2. Are the proposed conditions to the Modification Application sufficient to promote the purposes of Section 17A of the Exchange Act and to allow the Commission to adequately monitor the effects of EB's Clearing Agency Activities on the national system for the clearance and settlement of securities transactions? Why or why not?
3. EB has represented that its provision of the U.S. Equities Clearing Agency Activities would benefit U.S. Participants by providing a service to efficiently satisfy the New Collateral Regulations. Will the provision of the U.S. Equities Clearing Agency Activities provide those or other benefits? Will providing the service lead to lower costs, or higher costs, for U.S. Participants or other segments of the U.S. securities markets? What other benefits would U.S. Participants or other U.S. persons receive from these services?
4. Are there other providers of collateral management or related post-trade processing services that may be placed at a competitive advantage as a result of EB's account at DTC and the creation of DEGCL?
5. Similar to the volume limits placed on the U.S. Government Securities Clearing Agency Activities, should there be a volume limit on the U.S. Equities Clearing Agency Activities? If so, what should be the volume limit and why?
6. Are there potential issues or concerns that the Commission should consider? For example, differences between U.S. and Belgian law or other possible effects of the proposed Modification Application on the U.S. securities markets and investors.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/proposed.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number 601–01 on the subject line; or

Paper Comments

- Send paper comments to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. All submissions should refer to File Number 601–01.

To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/other.shtml*).

Copies of the submission, all subsequent amendments, all written statements with respect to the application that are filed with the Commission, and all written communications relating to the application between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Section, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m.

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number 601–01 and should be submitted on or before October 6, 2016.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[118]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–21245 Filed 9–2–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release Nos. 33–10200; 34–78726/August 30, 2016]

Order Making Fiscal Year 2017 Annual Adjustments to Registration Fee Rates

I. Background

The Commission collects fees under various provisions of the securities laws. Section 6(b) of the Securities Act of 1933 ("Securities Act") requires the Commission to collect fees from issuers on the registration of securities.[1] Section 13(e) of the Securities Exchange Act of 1934 ("Exchange Act") requires the Commission to collect fees on specified repurchases of securities.[2] Section 14(g) of the Exchange Act requires the Commission to collect fees on specified proxy solicitations and statements in corporate control transactions.[3] These provisions require the Commission to make annual adjustments to the applicable fee rates.

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[118] 17 CFR 200.30–3(a)(16).

[1] 15 U.S.C. 77f(b).

[2] 15 U.S.C. 78m(e).

II. Fiscal Year 2017 Annual Adjustment to Fee Rates

Section 6(b)(2) of the Securities Act requires the Commission to make an annual adjustment to the fee rate applicable under Section 6(b).[4] The annual adjustment to the fee rate under Section 6(b) of the Securities Act also sets the annual adjustment to the fee rates under Sections 13(e) and 14(g) of the Exchange Act.[5]

Section 6(b)(2) sets forth the method for determining the annual adjustment to the fee rate under Section 6(b) for fiscal year 2017. Specifically, the Commission must adjust the fee rate under Section 6(b) to a "rate that, when applied to the baseline estimate of the aggregate maximum offering prices for [fiscal year 2017], is reasonably likely to produce aggregate fee collections under [Section 6(b)] that are equal to the target fee collection amount for [fiscal year 2017]." That is, the adjusted rate is determined by dividing the "target fee collection amount" for fiscal year 2017 by the "baseline estimate of the aggregate maximum offering prices" for fiscal year 2017.

Section 6(b)(6)(A) specifies that the "target fee collection amount" for fiscal year 2017 is $585,000,000. Section 6(b)(6)(B) defines the "baseline estimate of the aggregate maximum offering prices" for fiscal year 2017 as "the baseline estimate of the aggregate maximum offering price at which securities are proposed to be offered pursuant to registration statements filed with the Commission during [fiscal year 2017] as determined by the Commission, after consultation with the Congressional Budget Office and the Office of Management and Budget. . . ."

To make the baseline estimate of the aggregate maximum offering price for fiscal year 2017, the Commission is using a methodology that has been used in prior fiscal years and that was developed in consultation with the Congressional Budget Office ("CBO") and Office of Management and Budget ("OMB").[6] Using this methodology, the Commission determines the "baseline estimate of the aggregate maximum offering price" for fiscal year 2017 to be $5,047,682,013,502. Based on this estimate, the Commission calculates the fee rate for fiscal 2017 to be $115.90 per million. This adjusted fee rate applies to Section 6(b) of the Securities Act, as well as to Sections 13(e) and 14(g) of the Exchange Act.

III. Effective Dates of the Annual Adjustments

The fiscal year 2017 annual adjustments to the fee rates applicable under Section 6(b) of the Securities Act and Sections 13(e) and 14(g) of the Exchange Act will be effective on October 1, 2016.[7]

IV. Conclusion

Accordingly, pursuant to Section 6(b) of the Securities Act and Sections 13(e) and 14(g) of the Exchange Act,[8]

IT IS HEREBY ORDERED that the fee rates applicable under Section 6(b) of the Securities Act and Sections 13(e) and 14(g) of the Exchange Act shall be $115.90 per million effective on October 1, 2016.

By the Commission.

Brent J. Fields,

Secretary.

Appendix A

Congress has established a target amount of monies to be collected from fees charged to issuers based on the value of their registrations. This appendix provides the formula for determining such fees, which the Commission adjusts annually. Congress has mandated that the Commission determine these fees based on the "aggregate maximum offering prices," which measures the aggregate dollar amount of securities registered with the Commission over the course of the year. In order to maximize the likelihood that the amount of monies targeted by Congress will be collected, the fee rate must be set to reflect projected aggregate maximum offering prices. As a percentage, the fee rate equals the ratio of the target amounts of monies to the projected aggregate maximum offering prices.

For 2017, the Commission has estimated the aggregate maximum offering prices by projecting forward the trend established in the previous decade. More specifically, an ARIMA model was used to forecast the value of the aggregate maximum offering prices for months subsequent to July 2016, the last month for which the Commission has data on the aggregate maximum offering prices.

The following sections describe this process in detail.

A. Baseline Estimate of the Aggregate Maximum Offering Prices for Fiscal Year 2017

First, calculate the aggregate maximum offering prices (AMOP) for each month in the sample (July 2006–July 2016). Next, calculate the percentage change in the AMOP from month to month.

Model the monthly percentage change in AMOP as a first order moving average process. The moving average approach allows one to model the effect that an exceptionally high (or low) observation of AMOP tends to be followed by a more "typical" value of AMOP.

Use the estimated moving average model to forecast the monthly percent change in AMOP. These percent changes can then be applied to obtain forecasts of the total dollar value of registrations. The following is a more formal (mathematical) description of the procedure:

1. Begin with the monthly data for AMOP. The sample spans ten years, from July 2006 to July 2016.

2. Divide each month's AMOP (column C) by the number of trading days in that month (column B) to obtain the average daily AMOP (AAMOP, column D).

3. For each month t, the natural logarithm of AAMOP is reported in column E.

4. Calculate the change in log(AAMOP) from the previous month as $\Delta_t = \log(\mathrm{AAMOP}_t) - \log(\mathrm{AAMOP}_{t-1})$. This approximates the percentage change.

5. Estimate the first order moving average model $\Delta_t = \alpha + \beta e_{t-1} + e_t$, where e_t denotes the forecast error for month t. The forecast error is simply the difference between the one-month ahead forecast and the actual realization of Δ_t. The forecast error is expressed as $e_t = \Delta_t - \alpha - \beta e_{t-1}$. The model can be estimated using standard commercially available software. Using least squares, the estimated parameter values are $\alpha = 0.002807020$ and $\beta = -0.82994$.

6. For the month of August 2016 forecast $\Delta_{t=8/16} = \alpha + \beta e_{t=7/16}$. For all subsequent months, forecast $\Delta_t = \alpha$.

7. Calculate forecasts of log(AAMOP). For example, the forecast of log(AAMOP) for October 2016 is given by $\mathrm{FLAAMOP}_{t=10/16} = \log(\mathrm{AAMOP}_{t=7/16}) + \Delta_{t=8/16} + \Delta_{t=9/16} + \Delta_{t=10/16}$.

8. Under the assumption that e_t is normally distributed, the n-step ahead forecast of AAMOP is given by $\exp(\mathrm{FLAAMOP}_t + \sigma_n^2/2)$, where σ_n denotes the standard error of the n-step ahead forecast.

9. For October 2016, this gives a forecast AAMOP of $19.614 billion (Column I), and a forecast AMOP of $411.9 billion (Column J).

10. Iterate this process through September 2017 to obtain a baseline estimate of the aggregate maximum offering prices for fiscal year 2017 of $5,047,682,013,502.

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[3] 15 U.S.C. 78n(g).

[4] 15 U.S.C. 77f(b)(2). The annual adjustments are designed to adjust the fee rate in a given fiscal year so that, when applied to the aggregate maximum offering price at which securities are proposed to be offered for the fiscal year, it is reasonably likely to produce total fee collections under Section 6(b) equal to the "target fee collection amount" specified in Section 6(b)(6)(A) for that fiscal year.

[5] 15 U.S.C. 78m(e)(4) and 15 U.S.C. 78n(g)(4).

[6] Appendix A explains how we determined the "baseline estimate of the aggregate maximum offering price" for fiscal year 2017 using our methodology, and then shows the arithmetical process of calculating the fiscal year 2017 annual adjustment based on that estimate. The appendix includes the data used by the Commission in making its "baseline estimate of the aggregate maximum offering price" for fiscal year 2017.

[7] 15 U.S.C. 77f(b)(4), 15 U.S.C. 78m(e)(6) and 15 U.S.C. 78n(g)(6).

[8] 15 U.S.C. 77f(b), 78m(e) and 78n(g).

B. Using the Forecasts From A to Calculate the New Fee Rate

1. Using the data from Table A, estimate the aggregate maximum offering prices between 10/01/16 and 9/30/17 to be $5,047,682,013,502.

2. The rate necessary to collect the target $585,000,000 in fee revenues set by Congress is then calculated as: $585,000,000 ÷ $5,047,682,013,502 = 0.000115895.

3. Round the result to the seventh decimal point, yielding a rate of 0.0001159 (or $115.90 per million).

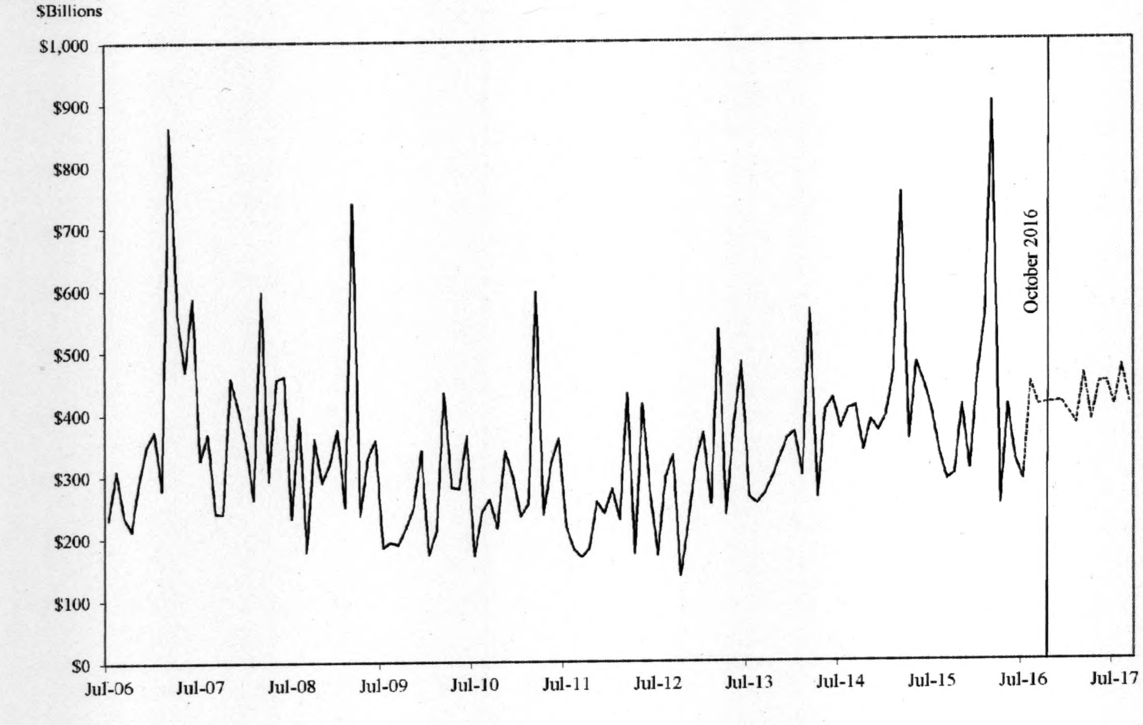
TABLE A—ESTIMATION OF BASELINE OF AGGREGATE MAXIMUM OFFERING PRICES

Fee rate calculation	
a. Baseline estimate of the aggregate maximum offering prices, 10/1/16 to 9/30/17 ($Millions)	5,047,682
b. Implied fee rate ($585 Million/a)	$115.90

Month (A)	# of trading days in month (B)	Aggregate maximum offering prices, in $millions (C)	Average daily aggregate max. offering prices (AAMOP) in $millions (D)	log(AAMOP) (E)	Log (change in AAMOP) (F)	Forecast log(AAMOP) (G)	Standard error (H)	Forecast AAMOP, in $millions (I)	Forecast aggregate maximum offering prices, in $millions (J)
				Data					
Jul–06	20	232,654	11,633	23.177	....	....	....	....	....
Aug–06	23	310,050	13,480	23.325	0.147	....	....	....	....
Sep–06	20	236,782	11,839	23.195	–0.130	....	....	....	....
Oct–06	22	213,342	9,697	22.995	–0.200	....	....	....	....
Nov–06	21	292,456	13,926	23.357	0.362	....	....	....	....
Dec–06	20	349,512	17,476	23.584	0.227	....	....	....	....
Jan–07	20	372,740	18,637	23.648	0.064	....	....	....	....
Feb–07	19	278,753	14,671	23.409	−0.239	....	....	....	....
Mar–07	22	862,786	39,218	24.392	0.983	....	....	....	....
Apr–07	20	562,103	28,105	24.059	−0.333	....	....	....	....
May–07	22	470,843	21,402	23.787	−0.272	....	....	....	....
Jun–07	21	586,822	27,944	24.053	0.267	....	....	....	....
Jul–07	21	326,612	15,553	23.468	−0.586	....	....	....	....
Aug–07	23	369,172	16,051	23.499	0.032	....	....	....	....
Sep–07	19	241,059	12,687	23.264	−0.235	....	....	....	....
Oct–07	23	239,652	10,420	23.067	−0.197	....	....	....	....
Nov–07	21	458,654	21,841	23.807	0.740	....	....	....	....
Dec–07	20	410,200	20,510	23.744	−0.063	....	....	....	....
Jan–08	21	354,433	16,878	23.549	−0.195	....	....	....	....
Feb–08	20	263,410	13,171	23.301	−0.248	....	....	....	....
Mar–08	20	596,923	29,846	24.119	0.818	....	....	....	....
Apr–08	22	292,534	13,297	23.311	−0.809	....	....	....	....
May–08	21	456,077	21,718	23.801	0.491	....	....	....	....
Jun–08	21	461,087	21,957	23.812	0.011	....	....	....	....
Jul–08	22	232,896	10,586	23.083	−0.730	....	....	....	....
Aug–08	21	395,440	18,830	23.659	0.576	....	....	....	....
Sep–08	21	177,636	8,459	22.858	−0.800	....	....	....	....
Oct–08	23	360,494	15,674	23.475	0.617	....	....	....	....
Nov–08	19	288,911	15,206	23.445	−0.030	....	....	....	....
Dec–08	22	319,584	14,527	23.399	−0.046	....	....	....	....
Jan–09	20	375,065	18,753	23.655	0.255	....	....	....	....
Feb–09	19	249,666	13,140	23.299	−0.356	....	....	....	....
Mar–09	22	739,931	33,633	24.239	0.940	....	....	....	....
Apr–09	21	235,914	11,234	23.142	−1.097	....	....	....	....
May–09	20	329,522	16,476	23.525	0.383	....	....	....	....
Jun–09	22	357,524	16,251	23.511	−0.014	....	....	....	....
Jul–09	22	185,187	8,418	22.854	–0.658	....	....	....	....
Aug–09	21	192,726	9,177	22.940	0.086	....	....	....	....
Sep–09	21	189,224	9,011	22.922	−0.018	....	....	....	....
Oct–09	22	215,720	9,805	23.006	0.085	....	....	....	....
Nov–09	20	248,353	12,418	23.242	0.236	....	....	....	....
Dec–09	22	340,464	15,476	23.463	0.220	....	....	....	....
Jan–10	19	173,235	9,118	22.933	−0.529	....	....	....	....
Feb–10	19	209,963	11,051	23.126	0.192	....	....	....	....
Mar–10	23	432,934	18,823	23.658	0.533	....	....	....	....
Apr–10	21	280,188	13,342	23.314	0.344	....	....	....	....
May–10	20	278,611	13,931	23.357	0.043	....	....	....	....
Jun–10	22	364,251	16,557	23.530	0.173	....	....	....	....
Jul–10	21	171,191	8,152	22.822	−0.709	....	....	....	....
Aug–10	22	240,793	10,945	23.116	0.295	....	....	....	....
Sep–10	21	260,783	12,418	23.242	0.126	....	....	....	....
Oct–10	21	214,988	10,238	23.049	−0.193	....	....	....	....
Nov–10	21	340,112	16,196	23.508	0.459	....	....	....	....
Dec–10	22	297,992	13,545	23.329	−0.179	....	....	....	....
Jan–11	20	233,668	11,683	23.181	−0.148	....	....	....	....
Feb–11	19	252,785	13,304	23.311	0.130	....	....	....	....
Mar–11	23	595,198	25,878	23.977	0.665	....	....	....	....
Apr–11	20	236,355	11,818	23.193	−0.784	....	....	....	....
May–11	21	319,053	15,193	23.444	0.251	....	....	....	....

Month (A)	# of trading days in month (B)	Aggregate maximum offering prices, in $millions (C)	Average daily aggregate max. offering prices (AAMOP) in $millions (D)	log(AAMOP) (E)	Log (change in AAMOP) (F)	Forecast log(AAMOP) (G)	Standard error (H)	Forecast AAMOP, in $millions (I)	Forecast aggregate maximum offering prices, in $millions (J)
Jun–11	22	359,727	16,351	23.518	0.073	....	....	....	....
Jul–11	20	215,391	10,770	23.100	−0.418	....	....	....	....
Aug–11	23	179,870	7,820	22.780	−0.320	....	....	....	....
Sep–11	21	168,005	8,000	22.803	0.023	....	....	....	....
Oct–11	21	181,452	8,641	22.880	0.077	....	....	....	....
Nov–11	21	256,418	12,210	23.226	0.346	....	....	....	....
Dec–11	21	237,652	11,317	23.150	−0.076	....	....	....	....
Jan–12	20	276,965	13,848	23.351	0.202	....	....	....	....
Feb–12	20	228,419	11,421	23.159	−0.193	....	....	....	....
Mar–12	22	430,806	19,582	23.698	0.539	....	....	....	....
Apr–12	20	173,626	8,681	22.884	−0.813	....	....	....	....
May–12	22	414,122	18,824	23.658	0.774	....	....	....	....
Jun–12	21	272,218	12,963	23.285	−0.373	....	....	....	....
Jul–12	21	170,462	8,117	22.817	−0.468	....	....	....	....
Aug–12	23	295,472	12,847	23.276	0.459	....	....	....	....
Sep–12	19	331,295	17,437	23.582	0.305	....	....	....	....
Oct–12	21	137,562	6,551	22.603	−0.979	....	....	....	....
Nov–12	21	221,521	10,549	23.079	0.476	....	....	....	....
Dec–12	20	321,602	16,080	23.501	0.422	....	....	....	....
Jan–13	21	368,488	17,547	23.588	0.087	....	....	....	....
Feb–13	19	252,148	13,271	23.309	−0.279	....	....	....	....
Mar–13	20	533,440	26,672	24.007	0.698	....	....	....	....
Apr–13	22	235,779	10,717	23.095	−0.912	....	....	....	....
May–13	22	382,950	17,407	23.580	0.485	....	....	....	....
Jun–13	20	480,624	24,031	23.903	0.322	....	....	....	....
Jul–13	22	263,869	11,994	23.208	−0.695	....	....	....	....
Aug–13	22	253,305	11,514	23.167	−0.041	....	....	....	....
Sep–13	20	267,923	13,396	23.318	0.151	....	....	....	....
Oct–13	23	293,847	12,776	23.271	−0.047	....	....	....	....
Nov–13	20	326,257	16,313	23.515	0.244	....	....	....	....
Dec–13	21	358,169	17,056	23.560	0.045	....	....	....	....
Jan–14	21	369,067	17,575	23.590	0.030	....	....	....	....
Feb–14	19	298,376	15,704	23.477	−0.113	....	....	....	....
Mar–14	21	564,840	26,897	24.015	0.538	....	....	....	....
Apr–14	21	263,401	12,543	23.252	−0.763	....	....	....	....
May–14	21	403,700	19,224	23.679	0.427	....	....	....	....
Jun–14	21	423,075	20,146	23.726	0.047	....	....	....	....
Jul–14	22	373,811	16,991	23.556	−0.170	....	....	....	....
Aug–14	21	405,017	19,287	23.683	0.127	....	....	....	....
Sep–14	21	409,349	19,493	23.693	0.011	....	....	....	....
Oct–14	23	338,832	14,732	23.413	−0.280	....	....	....	....
Nov–14	19	386,898	20,363	23.737	0.324	....	....	....	....
Dec–14	22	370,760	16,853	23.548	−0.189	....	....	....	....
Jan–15	20	394,127	19,706	23.704	0.156	....	....	....	....
Feb–15	19	466,138	24,534	23.923	0.219	....	....	....	....
Mar–15	22	753,747	34,261	24.257	0.334	....	....	....	....
Apr–15	21	356,560	16,979	23.555	−0.702	....	....	....	....
May–15	20	478,591	23,930	23.898	0.343	....	....	....	....
Jun–15	22	446,102	20,277	23.733	−0.166	....	....	....	....
Jul–15	22	402,062	18,276	23.629	−0.104	....	....	....	....
Aug–15	21	334,746	15,940	23.492	−0.137	....	....	....	....
Sep–15	21	289,872	13,803	23.348	−0.144	....	....	....	....
Oct–15	22	300,276	13,649	23.337	−0.011	....	....	....	....
Nov–15	20	409,690	20,485	23.743	0.406	....	....	....	....
Dec–15	22	308,569	14,026	23.364	−0.379	....	....	....	....
Jan–16	19	457,411	24,074	23.904	0.540	....	....	....	....
Feb–16	20	554,343	27,717	24.045	0.141	....	....	....	....
Mar–16	22	900,301	40,923	24.435	0.390	....	....	....	....
Apr–16	21	250,716	11,939	23.203	−1.232	....	....	....	....
May–16	21	409,992	19,523	23.695	0.492	....	....	....	....
Jun–16	22	321,219	14,601	23.404	−0.291	....	....	....	....
Jul–16	20	289,671	14,484	23.396	−0.008	....	....	....	....
Aug–16	23	....	....	....	....	23.632167	0.342	19,439	447,089
Sep–16	21	....	....	....	....	23.634974	0.347	19,526	410,051
Oct–16	21	....	....	....	....	23.637781	0.351	19,614	411,898
Nov–16	21	....	....	....	....	23.640588	0.356	19,703	413,754
Dec–16	21	....	....	....	....	23.643395	0.361	19,791	415,618
Jan–17	20	....	....	....	....	23.646202	0.366	19,880	397,610
Feb–17	19	....	....	....	....	23.649009	0.370	19,970	379,431
Mar–17	23	....	....	....	....	23.651816	0.375	20,060	461,381
Apr–17	19	....	....	....	....	23.654623	0.379	20,150	382,858
May–17	22	....	....	....	....	23.657430	0.384	20,241	445,306
Jun–17	22	....	....	....	....	23.660237	0.388	20,332	447,312
Jul–17	20	....	....	....	....	23.663044	0.392	20,424	408,479
Aug–17	23	....	....	....	....	23.665851	0.397	20,516	471,867
Sep–17	20	....	....	....	....	23.668658	0.401	20,608	412,168

Figure A
Aggregate Maximum Offering Prices Subject to Securities Act Section 6(b)
(Dashed Line Indicates Forecast Values)



[FR Doc. 2016–21268 Filed 9–2–16; 8:45 am]

BILLING CODE 8011–01–C

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78729; File No. SR–FINRA–2016–033]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change Amending Rule 12400 of the Code of Arbitration Procedure for Customer Disputes and Rule 13400 of the Code of Arbitration Procedure for Industry Disputes Relating to Broadening Chairperson Eligibility in Arbitration

August 30, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 18, 2016, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rule 12400 of the Code of Arbitration Procedure for Customer Disputes (''Customer Code'') and FINRA Rule 13400 of the Code of Arbitration Procedure for Industry Disputes (''Industry Code,'' and together with the Customer Code, the ''Codes'') to provide that an attorney arbitrator would be eligible for the chairperson roster if he or she completes chairperson training and serves as an arbitrator through award on at least one arbitration, instead of two arbitrations, administered by a self-regulatory organization (''SRO'') in which hearings were held.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

FINRA rules require chairpersons, who play a vital role in the administration of arbitration cases, to have arbitrator experience and training to ensure the quality and efficiency of arbitrations. FINRA Rules 12400 and 13400 address the Neutral List Selection System (''NLSS'')[3] and arbitrator rosters and provide, among other matters, that an arbitrator is eligible for the chairperson roster if he or she has completed chairperson training provided by FINRA and:

- Has a law degree and is a member of a bar of at least one jurisdiction and has served as an arbitrator through award on at least two arbitrations administered by an SRO in which hearings were held (an ''attorney arbitrator''); or
- Has served as an arbitrator through award on at least three arbitrations administered by an SRO in which hearings were held.

FINRA's Office of Dispute Resolution (''ODR'') offers 71 hearing locations, including at least one in each state of the United States, one in San Juan, Puerto Rico, and one in London, UK. ODR maintains a diverse roster of approximately 6,750 arbitrators, of which approximately 3,060 are currently classified as public. Approximately 1,000 of the 3,060 are chair-qualified. Despite the size of the public chairperson roster, forum users have raised concerns of a diminished public chairperson roster resulting from amendments to the ''public arbitrator'' definition that became effective on June 26, 2015.[4] As a result of the amended public arbitrator definition, FINRA reclassified approximately 13.8 percent (487 out of 3,512) of its public arbitrator roster as non-public and approximately 2.6 percent (93 out of 3,512) of its public arbitrator roster were temporarily disqualified and made ineligible for service.[5] Many of the arbitrators who were reclassified or disqualified were chair-qualified.

Currently, the public chairperson roster in each hearing location ranges from fewer than 40 to over 200. Forum users recognize the risk that when the caseload increases, the ratio of cases to qualified public chairpersons is higher and FINRA may not have a sufficient number of public chairpersons on its roster.

To expand the roster of public chairpersons in locations where the ratio of cases to qualified public chairpersons is higher, FINRA asks many public chairpersons to serve in multiple hearing locations. FINRA reimburses these chairpersons for their travel, lodging, and meals. However, party representatives have told FINRA staff that it is inconvenient to schedule hearings with out-of-town arbitrators. Moreover, during inclement weather, arbitrators may not be able to travel to the hearing location, which would then require parties to reschedule and incur additional costs. In addition, some forum users suggest that these arbitrators may also need instruction on the state laws, procedures, and customs for the hearing venue.

FINRA has had limited success in enrolling new public chairpersons. One reason is that for the last few years, FINRA's arbitration caseload has remained low, and public arbitrators were not serving on a sufficient number of cases through award to meet the case experience requirements for attorney arbitrators outlined above. In 2015, only 24% of cases closed by award. However, thus far in 2016, there has been an increase in case filings (up 20% compared to the same period in 2015). If this trend persists, the need for more public chairpersons could outpace the qualification pipeline under the current eligibility criteria.

Proposed Amendments to Rules 12400(c) and 13400(c)

FINRA is proposing to amend Rules 12400(c) and 13400(c) to provide that an attorney arbitrator would be eligible for the chairperson roster if he or she completes chairperson training and serves as an arbitrator through award on at least one arbitration, instead of two arbitrations, administered by an SRO in which hearings were held. Reducing the case experience requirement from two arbitrations to one arbitration could add more than 270 attorney arbitrators across 59 of the 71 hearing locations, resulting in a nearly 30 percent increase in the number of arbitrators who might be eligible to serve as public chairpersons once they take chairperson training.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The NLSS is a computer system that generates, on a random basis, lists of arbitrators from FINRA's rosters of arbitrators for the selected hearing location for each proceeding. FINRA maintains a roster of non-public arbitrators (as defined in FINRA Rules 12100(p) and 13100(p)), a roster of public arbitrators (as defined in FINRA Rules 12100(u) and 13100(u)), and a roster of arbitrators who are eligible to serve as chairperson of a panel.

[4] *See* Securities Exchange Act Release No. 74383 (February 26, 2015), 80 FR 11695 (Order Approving Filing No. SR–FINRA–2014–028) (in part narrowing the public arbitrator definition by adding disqualifications relating to, among other things, affiliations with the securities industry concerning an arbitrator's family member or place of employment).

[5] There were an estimated 2,932 public arbitrators after the amended public arbitrator definition became effective. Arbitrator recruitment since July 2015 added approximately 128 to the public arbitrator roster, thereby reaching approximately 3,060 public arbitrators as of this rule filing.

FINRA is also proposing to replace the bullets in Rules 12400 and 13400 with numbers for ease of citation.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act,[6] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change would protect investors and the public interest by potentially increasing the number of eligible public chairpersons in all hearing locations, without negatively impacting the quality of the chairperson rosters. The proposal would address concerns raised by forum users of FINRA's diminished public chairperson roster resulting from the amended public arbitrator definition and the inconvenience of scheduling hearings with out-of-town arbitrators.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Attorney arbitrators have the skillset to efficiently manage hearings and the experience to decide motions, among other matters. Their service as an arbitrator through award on one arbitration provides them with valuable experience regarding the arbitration forum. FINRA rules also require chairperson training before an attorney arbitrator becomes eligible to serve on a case as chairperson. The path to becoming chair-qualified is not mandatory however. ODR prompts candidates to register for chairperson training when they meet the other minimum qualifications. Any arbitrator who would like additional experience prior to serving as chairperson can defer the training until he or she gains that experience. In addition, ODR recently implemented a chairperson mentorship program to offer new chairpersons an additional resource for refining their chairperson skills. FINRA believes that by potentially increasing local chairpersons in hearing locations, FINRA would address forum users' concerns about scheduling out-of-town public chairpersons. Local arbitrators may also need less instruction on state laws, procedures, and customs. In addition, if the caseload increases, FINRA may not need to expand the use of public chairpersons from outside hearing locations, thereby avoiding additional forum user concerns.

The proposed rule change is expected to provide a greater selection of local chairpersons for forum users, thereby potentially lowering instances in which chairpersons must travel. In addition, during the arbitrator selection process, FINRA supplies all parties with Arbitrator Disclosure Reports[7] that include the arbitration case history for each potential arbitrator. Parties can strike arbitrators from the list for any reason. FINRA believes that the transparency of the Arbitrator Disclosure Report will continue to ensure that parties can make informed decisions regarding their chairperson selection and that the proposed rule change will increase the parties' choices.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2016–033 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2016–033. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549–1090, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2016–033 and should be submitted on or before September 27, 2016.

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[6] 15 U.S.C. 78o–3(b)(6).

[7] The Arbitrator Disclosure Report contains background information about the potential arbitrator, such as the arbitrator's name, classification, skills, employment, education, training, conflict information, and any publicly available awards the arbitrator issued.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–21253 Filed 9–2–16; 8:45 am]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2016–0037]

Agreement on Social Security Between the United States and Hungary; Entry into Force

AGENCY: Social Security Administration (SSA)

ACTION: Notice

SUMMARY: We are giving notice that an agreement coordinating the United States (U.S.) and Hungarian social security programs will enter into force on September 1, 2016. The agreement with Hungary, which was signed on February 3, 2015, is similar to U.S. social security agreements already in force with 25 other countries—Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Korea (South), Luxembourg, the Netherlands, Norway, Poland, Portugal, the Slovak Republic, Spain, Sweden, Switzerland, and the United Kingdom. Section 233 of the Social Security Act authorizes agreements of this type.

Like the other agreements, the U.S.-Hungarian agreement eliminates dual social security coverage. This situation exists when a worker from one country works in the other country and has coverage under the social security systems of both countries for the same work. When dual coverage occurs, the worker, the worker's employer, or both may be required to pay social security contributions to the two countries simultaneously without such agreements in force. Under the U.S.-Hungarian agreement, a worker who is sent by an employer in one country to work in the other country for five or fewer years remains covered only by the sending country. The agreement includes additional rules that eliminate dual U.S. and Hungarian coverage in other work situations.

The agreement also helps eliminate situations where workers suffer a loss of benefit rights because they have divided their careers between the two countries. Under the agreement, workers may qualify for partial U.S. benefits or partial Hungarian benefits based on combined (totalized) work credits from both countries.

Persons who wish to obtain copies of the agreement or want more information about its provisions may write to the Social Security Administration, Office of International Programs, Post Office Box 17741, Baltimore, MD 21235–7741 or visit the Social Security Web site at *www.socialsecurity.gov/international.*

Carolyn Colvin,

Acting Commissioner of Social Security.

[FR Doc. 2016–21348 Filed 9–2–16; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 9699]

Review of the Designation as a Foreign Terrorist Organization of Kata'ib Hizballah (and Other Aliases)

Based upon a review of the Administrative Record assembled pursuant to Section 219(a)(4)(C) of the Immigration and Nationality Act, as amended (8 U.S.C. 1189(a)(4)(C)) (''INA''), and in consultation with the Attorney General and the Secretary of the Treasury, I conclude that the circumstances that were the basis for the designation of the aforementioned organization as a Foreign Terrorist Organization have not changed in such a manner as to warrant revocation of the designation and that the national security of the United States does not warrant a revocation of the designation.

Therefore, I hereby determine that the designation of the aforementioned organization as a Foreign Terrorist Organization, pursuant to Section 219 of the INA (8 U.S.C. 1189), shall be maintained.

This determination shall be published in the **Federal Register**.

Dated: August 23, 2016.

John F. Kerry,

Secretary of State.

[FR Doc. 2016–21335 Filed 9–2–16; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Seventh Meeting of SC–233 Addressing Human Factors/Pilot Interface Issues for Avionics

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Seventh Meeting of the SC–233 addressing human factors/pilot interface issues for avionics.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Seventh Meeting of SC–233 Addressing Human Factors/Pilot Interface Issues for Avionics.

DATES: The meeting will be held September 27–29, 2016, 9:00 a.m. to 4:30 p.m.

ADDRESSES: The meeting will be held at: 1150 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Jennifer Iversen at *jiversen@rtca.org* or (202) 330–0662, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Seventh Meeting of the SC–233, Addressing Human Factors/Pilot Interface Issues for Avionics. The agenda will include the following:

September 27–29, 2016, 9:00 a.m. to 4:30 p.m.

Tuesday September 27, 2016

AM

- Introduction, Upcoming PMC Dates and Deliverable
- Review of TOR
- June meeting summary
- Roadmap for remaining items to be completed; notional schedule of activities remaining
- Consensus on document review process

PM

- Overview of the combined document and initial feedback
- Detailed review of document and identification of work to be done

Wednesday September 28, 2016

- Working Groups Break Out Sessions
- End of the Day Working Group Status Report Outs

Thursday September 29, 2016

AM

- Working Groups Break Out Session

PM

- Working Group Status

1. Working group leader reports
2. Follow-on actions

- Meeting Recap, Action Items, Key Dates

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[8] 17 CFR 200.30–3(a)(12).

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC on September 1, 2016.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2016–21403 Filed 9–2–16; 8:45 am]

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Part II

Department of Health and Human Services

Administration for Children and Families

45 CFR Chapter XIII
Head Start Performance Standards; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Chapter XIII

RIN 0970–AC63

Head Start Performance Standards

AGENCY: Office of Head Start (OHS), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule modernizes the Head Start Program Performance Standards, last revised in 1998. In the Improving Head Start for School Readiness Act of 2007, Congress instructed the Office of Head Start to update its performance standards and to ensure any such revisions to the standards do not eliminate or reduce quality, scope, or types of health, educational, parental involvement, nutritional, social, or other services programs provide. This rule responds to public comment, incorporates extensive findings from research and from consultation with experts, reflects best practices, lessons from program input and innovation, integrates recommendations from the Secretary's Advisory Committee Final Report on Head Start Research and Evaluation, and reflects the Obama Administration's deep commitment to improve the school readiness of young children. These performance standards will improve program quality, reduce burden on programs, and improve regulatory clarity and transparency. They provide a clear road map for current and prospective grantees to support high-quality Head Start services and to strengthen the outcomes of the children and families Head Start serves.

DATES: *Effective Date:* Provisions of this final rule become effective November 7, 2016.

Compliance Date(s): To allow programs reasonable time to implement certain performance standards, we phase in compliance dates over several years after this final rule becomes effective. In the **SUPPLEMENTARY INFORMATION** section below, we provide a table, Table 1: Compliance Table, which lists dates by which programs must implement specific standards.

FOR FURTHER INFORMATION CONTACT: Colleen Rathgeb, Division Director of Early Childhood Policy and Budget, Office of Early Childhood Development, at *OHS_Final_Rule@acf.hhs.gov* or (202) 401–1195 (not a toll free call). Deaf and hearing impaired individuals may call the Federal Dual Party Relay Service at 1–800–877–8339 between 8 a.m. and 7 p.m. Eastern Time.

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I. Executive Summary

Head Start currently provides comprehensive early learning services to more than 1 million children from birth to age five each year through more than 60,000 classes, home visitors, and family child care partners nationwide.[1] Since its inception in 1965, Head Start has been a leader in helping children from low-income families enter kindergarten more prepared to succeed in school and in life. Head Start is a central part of this Administration's effort to ensure all children have access to high-quality early learning opportunities and to eliminate the education achievement gap. This regulation is intended to improve the quality of Head Start services so that programs have a stronger impact on children's learning and development. It also is necessary to streamline and reorganize the regulatory structure to improve regulatory clarity and transparency so that existing grantees can more easily run a high-quality Head Start program and so that Head Start's operational requirements will be more transparent and seem less onerous to prospective grantees. In addition, this regulation is necessary to reduce the burden on local programs that can interfere with high-quality service delivery. We believe these regulatory changes will help ensure every child and family in Head Start receives high-quality services that will lead to greater success in school and in life.

In 2007, Congress mandated the Secretary to revise the program performance standards and update and raise the education standards.[2] Congress also prohibited elimination of, or any reduction in, the quality, scope, or types of services in the revisions.[3] Thus, these regulatory revisions are additionally intended to meet the statutory requirements Congress put forth in the bipartisan reauthorization of Head Start in 2007.

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[1] U.S. Department of Health and Human Services, Administration for Children and Families (2015). *Office of Head Start Program Information Report, 2014–2015.* Washington, DC: Author.

[2] *See https://www.congress.gov/congressional-report/110th-congress/house-report/439/1* and 42 U.S.C. 9836A(a)(1)(B).

[3] 42 U.S.C. 9836A(a)(2)(C)(ii).

The Head Start Program Performance Standards are the foundation on which programs design and deliver comprehensive, high-quality individualized services to support the school readiness of children from low-income families. The first set of Head Start Program Performance Standards was published in the 1970s. Since then, they have been revised following subsequent Congressional reauthorizations and were last revised in 1998. The program performance standards set forth the requirements local grantees must meet to support the cognitive, social, emotional, and healthy development of children from birth to age five. They encompass requirements to provide education, health, mental health, nutrition, and family and community engagement services, as well as rules for local program governance and aspects of federal administration of the program.

This final rule builds upon extensive consultation with researchers, practitioners, recommendations from the Secretary's Advisory Committee Final Report on Head Start Research and Evaluation,[4] and other experts, public comment, as well as internal analysis of program data and years of program input. In addition, program monitoring has also provided invaluable experience regarding the strengths and weaknesses of the previous program performance standards. Moreover, research and practice in the field of early childhood education has expanded exponentially in the 15 years since the program performance standards governing service delivery were last revised, providing a multitude of new insights on how to support improved child outcomes.

The Secretary's Advisory Committee, which consisted of expert researchers and practitioners chartered to provide "recommendations for improving Head Start program effectiveness" concluded early education programs, including Head Start, are capable of reducing the achievement gap, but that Head Start is not reaching its potential.[5] As part of their work, the Committee provided recommendations for interpreting the results of both the Head Start Impact Study (HSIS),[6] a randomized control trial study of children in Head Start in 2002 and 2003 through third grade, and the Early Head Start Research and Evaluation Project (EHSREP),[7] which was initiated in 1996 and followed children who were eligible to participate in Early Head Start. The Committee concluded that these findings should be interpreted in the context of the larger body of research that demonstrates Head Start and Early Head Start "are improving family well-being and improving school readiness of children at or below the poverty line in the U.S. today." [8] The Committee agreed the initial impact both Head Start and Early Head Start have demonstrated "are in line with the magnitude of findings from other scaled-up programs for infants and toddlers . . . and center-based programs for preschoolers . . ." but also acknowledged "larger impacts may be possible, *e.g.*, by increasing dosage in [Early Head Start] and Head Start or improving instructional factors in Head Start."[9] The Committee also addressed the finding that these impacts do not seem to persist into elementary school, stating the larger body of research on Head Start provides "evidence of long-term positive outcomes for those who participated in Head Start in terms of high school completion, avoidance of problem behaviors, avoidance of entry into the criminal justice system, too-early family formation, avoidance of special education, and workforce attachment." Overall, the report determined a key factor for Head Start to realize its potential is "making quality and other improvements and optimizing dosage within Head Start [and Early Head Start]." The final rule aims to capitalize on the advancements in research, available data, program input, public comment, and these recommendations in order to accomplish the critical goal of helping Head Start reach its full potential so more children reach kindergarten ready to succeed.

This final rule reorganizes previous program performance standards to make it easier for grantees to implement them and for the public to understand the broad range of Head Start program services. Our previous program performance standards consisted of 1,400 provisions organized in 11 different sections that were amended in a partial or topical fashion over the past 40 years. This approach resulted in a somewhat opaque set of requirements that were unnecessarily challenging to interpret and overburdened grantees with process-laden rules.

This rule has four distinct sections: (1) *Program Governance,* which outlines the requirements imposed by the Head Start Act (the "Act") on Governing Bodies and Policy Councils to ensure well-governed Head Start programs; (2) *Program Operations,* which outlines all of the operational requirements for serving children and families, from the universe of eligible children and the services they must be provided in education, health, and family and community engagement, to the way programs must use data to improve the services they provide; (3) *Financial and Administrative Requirements,* which lays out the federal requirements Head Start programs must adhere to because of overarching federal requirements or specific provisions imposed in the Act; and (4) *Federal Administrative Procedures,* which governs the procedures the responsible HHS official takes to determine the results of competition for all grantees, any actions against a grantee, whether a grantee needs to compete for renewed funding, and other transparency-related procedures required in the Act.

We also reorganized specific sections and streamlined provisions to make Head Start requirements easier to understand for all interested parties—grantees, potential grantees, other early education programs, and members of the general public. We reorganized subparts and their sections to eliminate redundancy, and we grouped together related requirements. Additionally, we systematically addressed the fact that many of our most critical provisions were buried in subparts that made them difficult to find and interpret, and did not reflect their centrality to the provision of high-quality services. For example, we created new subparts or sections to highlight and expand, where necessary, upon these important requirements.

We also streamlined requirements and minimized administrative burden on local programs. In total, we significantly reduced the number of regulatory requirements without compromising quality. We give programs greater flexibility to determine how best to achieve their goals and administer a high-quality Head Start program without reducing expectations for children and families. We anticipate these changes will help move Head Start away from a compliance-oriented culture to an outcomes-focused one. Furthermore, we believe this approach will support better collaboration with other programs and funding streams. We recognize that grantees deliver services through a variety of modalities including child care and state pre-kindergarten programs. Additionally, we removed other overly prescriptive requirements related to governing bodies, appeals, and audits.

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[4] *Advisory Committee on Head Start Research and Evaluation: Final Report.* (2012). Washington, DC: Office of Head Start, Administration for Children and Families, U.S. Department of Health and Human Services. *See https://www.acf.hhs.gov/sites/default/files/opre/eval_final.pdf.*

[5] *Ibid,* (p.1).

[6] Puma, M., Bell, S., Cook, R., Heid, C., Broene, P., Jenkins, F., & Downer, J. (2012). *Third grade follow-up to the Head Start impact study final report.* U.S. Department of Health and Human Services Office of Planning, Research and Evaluation.

[7] Cohen, R.C., Vogel, C.A., Xue, Y., Moiduddin, E.M., Carlson, B.L., Twin Peaks Partners, L.L.C., & Kisker, E.E. (2010). *Early Head Start Children in Grade 5: Long-Term Follow-Up of the Early Head Start Research and Evaluation Project Study Sample.* Washington, DC: U.S. Department of Health and Human Services, Administration for Children and Families, Office of Planning, Research, and Evaluation, (6933).

[8] *Advisory Committee on Head Start Research and Evaluation: Final Report.* (2012). Washington, DC: Office of Head Start, Administration for Children and Families, U.S. Department of Health and Human Services. *See https://www.acf.hhs.gov/sites/default/files/opre/eval_final.pdf.*

[9] *Ibid.* (p. 30).

We include several provisions to support local flexibility to meet community needs and to promote innovation and research. We give Head Start programs additional flexibility in the structural requirements of program models, such as group size and ratios. Further, we permit local variations for effective and innovative curriculum and professional development models, giving flexibility from some of these requirements if the Head Start program works with research experts and evaluates the effectiveness of their model. We also support local innovation through a process to waive individual eligibility verification requirements, which will allow better coordination with local early education programs without reducing quality. Collectively, these changes will allow for the development of innovative program models, alleviate paperwork burdens, and support mixed income settings.

We believe the benefits of these changes will be significant for the children and families Head Start serves. Strengthening Head Start standards will improve child outcomes and promote greater success in school as well as produce higher returns on taxpayer investment. Reorganizing, streamlining, and reducing the requirements in the regulation will make Head Start less burdensome for existing grantees and more approachable for potential grantees, which may result in more organizations competing for Head Start grants. These changes are central to the Administration's belief that every child deserves an opportunity to succeed.

II. Tables

Table 1: Compliance Table

PERFORMANCE STANDARD	COMPLIANCE DATE
Early Head Start center-based service duration (unless granted a waiver under §1302.24) **§1302.21(c)(1):** By August 1, 2018, a program must provide 1,380 annual hours of planned class operations for all enrolled children. A program that is designed to meet the needs of young parents enrolled in public school settings may meet the service duration requirements in §1302.21(c)(1)(i) if it operates a center-based program schedule during the school year aligned with its local education agency requirements and provides regular home-based services during the summer break.	**August 1, 2018**
Head Start center-based service duration: **50 percent at 1,020 annual hours** (unless granted a waiver under §1302.24) **§1302.21(c)(2)(iii) and (v):** By August 1, 2019, a program must provide 1,020 annual hours of planned class operations over the course of at least eight months per year for at least 50 percent of its Head Start center-based funded enrollment. A Head Start program providing fewer than 1,020 annual hours of planned class operations or fewer than eight months of service is considered to meet the requirements described in paragraphs §1302.21(c)(2)(iii) and (iv) if its program schedule aligns with the annual hours required by its local education agency for grade one and such alignment is necessary to support partnerships for service delivery.	**August 1, 2019**
Head Start center-based service duration: **100 percent at 1,020 annual hours** (unless granted a waiver under §1302.24) **§1302.21(c)(2)(iv):** By August 1, 2021, a program must provide 1,020 annual hours of planned class operations over the course of at least eight months per year for all of its Head Start center-based funded enrollment.	**August 1, 2021**
Early Head Start home-based service duration (unless granted a waiver under §1302.24)	

§1302.22(c)(1): By August 1, 2017, an Early Head Start home-based program must provide one home visit per week per family that lasts at least an hour and a half and provide a minimum of 46 visits per year; and, provide, at a minimum, 22 group socialization activities distributed over the course of the program year.	**August 1, 2017**
Curricula for center-based and family child care programs **§1302.32(a)(1)(ii) and (iii):** Implement curricula that are aligned with the Head Start Early Learning Outcomes Framework: Ages Birth to Five and, as appropriate, state early learning and development standards; and are sufficiently content-rich to promote measurable progress toward development and learning outlined in the Framework; and, have an organized developmental scope and sequence that include plans and materials for learning experiences based on developmental progressions and how children learn. **§1302.32(a)(2):** A program must support staff to effectively implement curricula and at a minimum monitor curriculum implementation and fidelity, and provide support, feedback, and supervision for continuous improvement of its implementation through the system of training and professional development. **§1302.32(b):** A program that chooses to make significant adaptations to a curriculum or a curriculum enhancement described in §1302.32(a)(1) to better meet the needs of one or more specific populations must use an external early childhood education curriculum or content area expert to develop such significant adaptations. A program must assess whether the adaptation adequately facilitates progress toward meeting school readiness goals, consistent with the process described in §1302.102(b) and (c).	**August 1, 2017**
Assessment **§1302.33(b)(1) through (3):** A program must conduct standardized and structured assessments, which may be observation-based or direct, for each child that provide ongoing information to evaluate the child's developmental level and progress in outcomes aligned to the goals described in the Head Start Early Learning Outcomes Framework: Ages Birth to Five. Such assessments must result in usable information for teachers, home visitors, and parents and be conducted with sufficient frequency to allow for individualization within the program year. A program must regularly use information from §1302.33(b)(1) along with informal teacher observations and additional information from family and staff, as relevant, to determine a child's strengths and needs, inform and adjust strategies to better support individualized learning and improve	**August 1, 2017**

teaching practices in center-based and family child care settings, and improve home visit strategies in home-based models. If warranted from the information gathered from §1302.33(b)(1) and (2) and with direct guidance from a mental health or child development professional and a parent's consent, a program must refer the child to the local agency responsible for implementing IDEA for a formal evaluation to assess a child's eligibility for services under IDEA. **§1302.33(c)(2) and (3):** If a program serves a child who speaks a language other than English a program must use qualified bilingual staff, contractor, or consultant to: • Assess language skills in English and in the child's home language, to assess both the child's progress in the home language and in English language acquisition; • Conduct screenings and assessments for domains other than language skills in the language or languages that best capture the child's development and skills in the specific domain; and, • Ensure those conducting the screening or assessment know and understand the child's language and culture and have sufficient skill level in the child's home language to accurately administer the screening or assessment and to record and understand the child's responses, interactions, and communications. If a program serves a child who speaks a language other than English and qualified bilingual staff, contractors, or consultants are not able conduct screenings and assessments, a program must use an interpreter in conjunction with a qualified staff person to conduct screenings and assessments as described in §1302.33(c)(2)(i) through (iii).	
Curriculum for home-based programs **§1302.35(d)(1) through (3):** A program that operates the home-based option must: • Ensure home-visiting and group socializations implement a developmentally appropriate research-based early childhood home-based curriculum that: o Promotes the parent's role as the child's teacher through experiences focused on the parent-child relationship and, as appropriate, the family's traditions, culture, values, and beliefs; o Aligns with the Head Start Early Learning Outcomes Framework: Ages Birth to Five and, as appropriate, state early learning standards, and, is sufficiently content-rich within the Framework to promote measurable progress toward goals outlined in the Framework; and, o Has an organized developmental scope and sequence that	**August 1, 2017**

includes plans and materials for learning experiences based on developmental progressions and how children learn. • Support staff in the effective implementation of the curriculum and at a minimum monitor curriculum implementation and fidelity, and provide support, feedback, and supervision for continuous improvement of its implementation through the system of training and professional development. o If a program chooses to make significant adaptations to a curriculum or curriculum enhancement to better meet the needs of one or more specific populations, a program must partner with early childhood education curriculum or content experts; and, assess whether the adaptation adequately facilitates progress toward meeting school readiness goals consistent with the process described in §1302.102(b) and (c).	
Quality Rating and Improvement Systems (QRIS) and Data systems **§1302.53(b)(2):** A program, with the exception of American Indian and Alaska Native programs, must participate in its state or local Quality Rating and Improvement System (QRIS) if: • Its state or local QRIS accepts Head Start monitoring data to document quality indicators included in the state's tiered system; • Participation would not impact a program's ability to comply with the Head Start Program Performance Standards; and, • The program has not provided the Office of Head Start with a compelling reason not to comply with this requirement. **§1302.53(b)(3):** **Data systems.** A program, with the exception of American Indian and Alaska Native programs unless they would like to and to the extent practicable, should integrate and share relevant data with state education data systems, to the extent practicable, if the program can receive similar support and benefits as other participating early childhood programs.	**August 1, 2017**
Complete background check procedures **§1302.90(b)(2):** A program has 90 days after an employee is hired to complete the background check process by obtaining whichever check listed in §1302.90(b)(1) was not obtained prior to the date of hire; and, child abuse and neglect state registry check, if available. **§1302.90(b)(4):** A program must ensure a newly hired employee, consultant, or contractor does not have unsupervised access to children until the complete background check process described in §1302.90(b)(1) through (3) is complete. **§1302.90(b)(5):** A program must conduct the complete background check for each employee, consultant, or contractor at least once every five years which	**August 1, 2017**

must include each of the four checks listed in §1302.90(b)(1) and (2), and review and make employment decisions based on the information as described in §1302.90(b)(3), unless the program can demonstrate to the responsible HHS official that it has a more stringent system in place that will ensure child safety.	
Child Development Specialist staff qualification **§1302.91(e)(4)(ii):** By August 1, 2018, a child development specialist, as required for family child care in §1302.23(e), must have, at a minimum, a baccalaureate degree in child development, early childhood education, or a related field.	**August 1, 2018**
Home visitor staff qualifications **§1302.91(e)(6)(i):** A program must ensure home visitors providing home-based education services have a minimum of a home-based CDA credential or comparable credential, or equivalent coursework as part of an associate's or bachelor's degree.	**August 1, 2018**
Coordinated coaching strategy and coaching staff qualifications **§1302.92(c):** A program must ensure coaches meet staff qualifications in §1302.91(f) and must implement a research-based, coordinated coaching strategy for education staff as described in §1302.92(c).	**August 1, 2017**
Management of program data **§1302.101(b)(4):** At the beginning of each program year, and on an ongoing basis throughout the year, a program must design and implement program-wide coordinated approaches that ensure the management of program data to effectively support the availability, usability, integrity, and security of data. A program must establish procedures on data management, and have them approved by the governing body and policy council, in areas such as quality of data and effective use and sharing of data, while protecting the privacy of child records in accordance with subpart C of part 1303 and applicable federal, state, local, and tribal laws.	**August 1, 2017**

Table 2—Redesignation Table

This final rule reorganizes and redesignates the Head Start Program Performance Standards under subchapter B at 45 CFR chapter XIII. We believe our efforts provide current and prospective grantees an organized road map on how to provide high-quality Head Start services.

To help the public readily locate sections and provisions from the previous performance standards that are reorganized and redesignated, we included redesignation and distribution tables in the NPRM. The redesignation table listed the previous section and identified the section we proposed would replace it. The distribution table in the NPRM listed previous provisions and showed whether we removed, revised, or redesignated them. We believe the public may continue to find the redesignation table useful here, so we included an updated version of it below.

TABLE 2—REDESIGNATION TABLE

Previous section	New section
1301.1	1303.2
1301.20	1305
1301.10	1303.3
1301.11	1303.12
1301.20	1303.4
1301.21	1303.4
1301.30	1303.10
1301.31	1302.90, 1302.102
1301.32	1303.5
1301.33	1303.31
1301.34	1304.5, 1304.7
1302.1	1304.1
1302.2	1305
1302.5	1304.2, 1304.3, 1304.4
1302.10	1304.20
1302.11	1304.20
1302.30	1304.30
1302.31	1304.31
1302.32	1304.32
1303.1	1304.1, 1303.30
1303.2	1305
1303.10	1304.1
1303.11	1304.3
1303.12	1304.4
1303.14	1304.5
1303.21	1304.6
1303.22	1304.6
1304.1	1302.1
1304.3	1305
1304.20	1302.42, 1302.33, 1302.41, 1302.61, 1302.46, 1302.63
1304.21	1302.30, 1302.31, 1302, 1302.35, 1302.60, 1302.90, 1302.34, 1302.33, 1302.46, 1302.21
1304.22	1302.47, 1302.92, 1302.15, 1302.90, 1302.41, 1302.42, 1302.46
1304.23	1302.42, 1302.44, 1302.31, , 1302.90, , 1302.46
1304.24	1302.46, 1302.45
1304.40	1302.50, 1302.52, 1302.80, 1302.18, 1302.34, 1302.51, 1302.30, 1302.18, 1302.81, 1302.46, 1302.52, 1302.70, 1302.71, 1302.72, 1302.22, 1302.82
1304.41	1302.53, 1302.63, 1302.70, 1302.71
1304.50	1301.1, 1301.3 1302.102, , 1301.4
1304.51	1302.101, 1302.90, 1303.23, 1302.102, 1301.3, 1303.32
1304.52	1302.101, 1302.91, 1302.90, 1302.91, 1302.21, 1303.3, 1302.93, 1302.94, 1302.92, 1301.5
1304.53	1302.31, 1302.21, 1302.47, 1302.22, 1302.23
1304.60	1302.102, 1304.2
1305.1	1302.10
1305.2	1305
1305.3	1302.11, 1302.102, 1302.20
1305.4	1302.12
1305.5	1302.13, 1302.14,
1305.6	1302.14
1305.7	1302.12, 1302.15, 1302.70
1305.8	1302.16
1305.9	1302.18
1305.10	1304.4
1306.3	1305
1306.20	1302.101, 1302.21, 1302.90, 1302.23, 1302.20
1306.21	1302.91
1306.23	1302.92
1306.30	1302.20, 1302.21, 1302.22, 1302.23
1306.31	1302.20
1306.32	1302.21, 1302.24, 1302.17, 1302.102, 1302.34, 1302.18
1306.33	1302.22, 1302.101 , 1302.91, 1302.35, 1302.44, 1302.23, 1302.31, 1301.4, 1302.47, 1302.45, 1302.24
1307.1	1304.10

TABLE 2—REDESIGNATION TABLE—Continued

Previous section	New section
1307.2	1305
1307.3	1304.11
1307.4	1304.12
1307.5	1304.13
1307.6	1304.14
1307.7	1304.15
1307.8	1304.16
1308.1	1302.60
1308.3	1305
1308.4	1302.101, 1302.61, 1302.63, 1303.75
1308.5	1302.12, 1302.13
1308.6	1302.33, 1302.42, 1302.34, 1302.33
1308.18	1302.47
1308.21	1302.61, 1302.62, 1302.34
1309.1	1303.40
1309.2	1303.41
1309.3	1305
1309.4	1303.42, 1303.44, 1303.45, 1303.48, 1303.50
1309.21	1305, 1303.51, 1303.48, 1303.50, 1303.46, 1303.47, 1303.48, 1303.55, 1303.3
1309.22	1303.49, 1303.51
1309.31	1303.44, 1303.47
1309.33	1303.56
1309.40	1303.53
1309.41	1303.54
1309.43	1303.43
1309.52	1303.55
1309.53	1303.56
1310.2	1303.70
1310.3	1305
1310.10	1303.70, 1303.71, 1303.72
1310.14	1303.71
1310.15	1303.72
1310.16	1303.72
1310.17	1303.72
1310.20	1303.73
1310.21	1303.74
1310.22	1303.75
1310.23	1303.70

III. Background

a. Statutory Authority

This final rule is published under the authority granted to the Secretary of the Department of Health and Human Services under sections 640, 641A, 642, 644, 645, 645A, 646, 648A, and 649 of the Head Start Act, Public Law 97–35, 95 Stat. 499 (42 U.S.C. 9835, 9836a, 9837, 9839, 9840, 9840a, 9841, 9843a, and 9844), as amended by the Improving Head Start for School Readiness Act of 2007, Public Law 110–134, 121 Stat. 1363. In these sections, the Secretary is required to establish performance standards for Head Start and Early Head Start programs, as well as federal administrative procedures. Specifically, the Act requires the Secretary to ". . . modify, as necessary, program performance standards by regulation applicable to Head Start agencies and programs. . ." and explicitly directs a number of modifications, including "scientifically based and developmentally appropriate education performance standards related to school readiness that are based on the Head Start Child Outcomes Framework" and to "consult with experts in the fields of child development, early childhood education, child health care, family services . . ., administration, and financial management, and with persons with experience in the operation of Head Start programs."[10] Not only did the Act mandate such significant revisions, there was also bipartisan and bicameral agreement in Congress that its central purpose was to update and raise the education standards and practices in Head Start programs.[11] [12] As such, these program performance standards substantially build upon and improve the standards related to the education of children in Head Start programs.

b. Purpose of This Rule

This rule meets the statutory requirements Congress put forth in its 2007 bipartisan reauthorization of Head Start and addresses Congress's mandate that called for the Secretary to review and revise the Head Start Program Performance Standards.[13] Program performance standards are the foundation upon which Head Start programs design and deliver comprehensive, high-quality individualized services to support the school readiness of children from low-income families. They set forth requirements local grantees must meet to support the cognitive, social, emotional, and healthy development of children from birth to age five. They encompass requirements to provide education, health, mental health, nutrition, and family and community engagement services, as well as rules for local program governance and aspects of federal administration of the program.

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[10] *See* section 42 U.S.C. 9836A (a)(1) and (2).

[11] *See http://beta.congress.gov/crec/2007/11/14/CREC-2007-11-14-pt1-PgH13876-4.pdf.*

[12] *See http://beta.congress.gov/crec/2007/11/14/CREC-2007-11-14-pt1-PgS14375-2.pdf.*

[13] *See http://beta.congress.gov/crec/2007/11/14/CREC-2007-11-14-pt1-PgS14375-2.pdf.*

Program performance standards in this final rule build upon field knowledge and experience to codify best practices and ensure Head Start programs deliver high-quality services to the children and families they serve.

This final rule strengthens program standards so that all children and families receive high-quality services that will have a stronger impact on child development and outcomes and family well-being. The program performance standards set higher standards for curriculum, staff development, and program duration, all based on research and effective practice, while maintaining Head Start's core values of family engagement, parent leadership, and providing important comprehensive services to our nation's neediest children. At the same time, the final rule makes program requirements easier for current and future program leaders to understand and reduces administrative burden so that Head Start directors can focus on delivering high-quality early learning programs that help put children onto a path of success.

c. Rulemaking and Comment Processes

We sought extensive input to develop this final rule. We began the rulemaking process with consultations, listening sessions, and focus groups with Head Start staff, parents, and program administrators, along with child development and subject matter experts, early childhood education program leaders, and representatives from Indian tribes, migrant and seasonal communities, and other constituent groups. We heard from tribal leaders at our annual tribal consultations. We studied the final report of the Secretary's Advisory Committee on Head Start Research. We consulted with national organizations and agencies with particular expertise and longstanding interests in early childhood education. In addition, we analyzed the types of technical assistance requested by and provided to Head Start agencies and programs. We reviewed findings from monitoring reports and gathered information from programs and families about the circumstances of populations Head Start serves. We considered advances in research-based practices with respect to early childhood education and development, and the projected needs of expanding Head Start services. We also drew upon the expertise of federal agencies and staff responsible for related programs in order to obtain relevant data and advice on how to promote quality across all Head Start settings and program options. We reviewed the studies on developmental outcomes and assessments for young children and on the workforce by the National Academy of Sciences.[14] [15] We also reviewed the standards and performance criteria established by state Quality Rating and Improvement Systems, national organizations, and policy experts in early childhood development, health, safety, maternal health, and related fields.

We published a notice of proposed rulemaking (NPRM) on June 19, 2015 to solicit comments from the public. We extended the notice of proposed rulemaking comment period 30 days past our original deadline to September 17, 2015, to allow for more feedback from parents, grantees, and the Head Start community in general. We received, analyzed, and considered approximately 1,000 public comments to develop this final rule. Commenters included Head Start parents, staff, and management; national, regional, and state Head Start associations; researchers; early childhood, health, and parent organizations; policy think tanks; philanthropic foundations; Members of Congress; and other interested parties.

d. Overview of Major Changes From the NPRM

The public comments addressed a wide range of issues. We made many changes to the program performance standards in response to those comments, which range from minor to significant. The most significant changes fall under several categories: Service duration, the central and critical role of parents in Head Start, staff qualifications to support high-quality, comprehensive service delivery, and health promotion.

First, we made changes to this final rule in response to the many public comments we received on the proposal to increase the duration of services children receive in Head Start. The changes to the service duration requirements in the final rule reflect concerns about local flexibility and access to Head Start for low-income children and their families. Instead of requiring all Head Start center-based programs to operate for at least 6 hours per day and 180 days per year as proposed in the NPRM, we changed the requirement to a minimum of 1,020 annual hours of planned class operations, which grantees will phase in for all of their center-based slots over five years. Similarly for Early Head Start, we changed the requirement in the NPRM for center-based programs to operate at least 6 hours per day and 230 days per year to 1,380 annual hours in this rule, and allow two years for programs to plan and implement this increase in service duration. These requirements balance the importance of increasing service duration with allowing greater local flexibility and more time for communities to adapt and potential funding to be secured.

Research supports the importance of longer preschool duration in achieving meaningful child outcomes and preparing children for success in school.[16] [17] [18] [19] [20] [21] [22] [23] Shorter preschool programs may not have as much time to adequately support strong early learning outcomes for children and provide necessary comprehensive services.[24] [25] [26] In addition, the long summer break in most Head Start programs likely results in summer learning loss that undermines gains children make during the program year.[27] [28] [29] Furthermore, part-day programs can undermine parents' job search, job training, and employment opportunities.

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[14] National Academy of Sciences (October, 2008) *Early Childhood Assessment: Who, What, How.* Washington, DC.

[15] National Academy of Sciences (April, 2015) *Transforming the Workforce for Children Birth through Age 8: A Unifying Foundation.* Washington, DC.

[16] Robin, K.B., Frede, E.C., Barnett, W.S. (2006.) *NIEER Working Paper—Is More Better? The Effects of Full-Day vs Half-Day Preschool on Early School Achievement.* NIEER.

[17] Votruba-Drzal, E., Li-Grining, C.P., & Maldonado-Carreno, C. (2008). A developmental perspective on full- versus part-day kindergarten and children's academic trajectories through fifth grade. *Child Development, 79,* 957–978.

[18] Lee, V.E., Burkam, D.T., Ready, D.D., Honigman, J., & Meisels, S.J. (2006). Full-day vs. half-day kindergarten: In which program do children learn more? *American Journal of Education, 112,* 163–208.

[19] Li, W. (2012). *Effects of Head Start hours on children's cognitive, pre-academic, and behavioral outcomes: An instrumental variable analysis.* Presented at Fall 2012 Conference of the Association for Public Policy Analysis and Management.

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[21] Walters, C.R. (2015). Inputs in the Production of Early Childhood Human Capital: Evidence from Head Start, *American Economic Journal: Applied Economics, 7*(4), 76–102.

[22] Wasik, B. & Snell, E. (2015). *Synthesis of Preschool Dosage: Unpacking How Quantity, Quality and Content Impacts Child Outcomes.* Temple University, Philadelphia, PA.

[23] Yoshikawa, H., Weiland, C., Brooks-Gunn, J., Burchinal, M.R., Espinosa, L.M., Gormley, W.T., Ludwig, J., Magnuson, K.A., Phillips, D., & Zaslow, M.J. (2013). *Investing in Our Future: The Evidence Base on Preschool Education.* Policy Brief. Foundation for Child Development.

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[25] Lee, V.E., Burkam, D.T., Ready, D.D., Honigman, J., & Meisels, S.J. (2006). Full-Day versus Half-Day Kindergarten: In Which Program Do Children Learn More? *American Journal of Education, 112(2),* 163–208.

[26] Walston, J.T., and West, J. (2004). *Full-day and Half-day Kindergarten in the United States:*

In the NPRM, we proposed to increase the positive impact of Head Start programs serving three- to five-year-olds by increasing the minimum hours and days of operation and to codify long-standing interpretation of continuous services for programs that serve infants and toddlers, in concert with increasing standards for educational quality. Specifically, the NPRM proposed to require programs to serve three- to five-year-olds for at least 6 hours per day and 180 days per year and to require programs to serve infants and toddlers for a minimum of 6 hours per day and 230 days per year. Our proposal was consistent with research demonstrating the necessity of adequate instructional time to improve child outcomes and aligned with recommendations from the Secretary's Advisory Committee.[30] [31] [32] [33] [34] [35] However, though the research is clear that longer duration matters, there is no clarity on an exact threshold or combination of hours and days needed to achieve positive child outcomes. Therefore, in response to a significant number of public comments on the NPRM, including comments from the national, state, and regional Head Start associations, the final rule defines full school day and full school year services as 1,020 annual hours for Head Start programs and defines continuous services as 1,380 annual hours for Early Head Start programs, instead of setting a minimum number of hours per day and days per year for each program. These adjusted requirements will give programs more flexibility to design their program schedules to better meet children and community needs as well as align with local school district calendars, where appropriate.

To further address the comments about service duration and ensure a smooth transition for children and families, the final rule also includes a staggered approach to increasing service duration for Head Start preschoolers over the next five years. This gradual transition will allow programs more time to plan and implement changes while also increasing families' access to full school day Head Start services and ensuring more children receive the high-quality early learning services to help them arrive at kindergarten ready to succeed. The final rule also gives the Secretary the authority to reduce the proportion of each grantee's center-based slots required to operate for a full school day and full school year if the Secretary determines that such a reduction is needed to avert a substantial reduction in slots. We believe the requirements in the final rule strike an appropriate balance between setting the policy research demonstrates will best support positive outcomes for children and families, while minimizing reduction in the number of children and families Head Start can serve.

Second, we received comments that expressed concern that the proposed changes to family engagement services and governance would result in a reduction in emphasis on family engagement processes, parent leadership, and parent influence on program policy. This was not our intent. The intent of the NPRM was for the family engagement standards to incorporate the changes made to governance in the 2007 reauthorization and align with the groundbreaking work Head Start has led through the development of the Parent, Family, and Community Engagement Framework. Family engagement has always been at the foundation of Head Start, and as such, the final rule retains many of the proposed improvements to family services that integrate research-based practices and provide greater local flexibility to help programs better meet family needs. However, given the perception that the changes would limit the role of parents and families in Head Start, the final rule includes several changes to more effectively reflect and maintain the important role of Head Start parents in leading Head Start programs, as well as the importance of family engagement to the growth and success of Head Start children. Specifically, we restore a requirement for parent committees, maintain and strengthen family partnership services (including goal setting), and strengthen the requirements for impasse procedures to make it clear that the policy council plays a leadership role in the administration of programs, rather than functioning in an advisory capacity. It is our expectation that the revisions to the final rule will ensure all grantees, programs, and parents understand the foundational role parents of Head Start children play in shaping the program at the local and national level.

Third, this final rule includes several changes in response to comments that suggested Head Start should use the revision of the program performance standards to set a higher bar for the delivery of quality comprehensive services. Specifically, this final rule includes a greater emphasis on staff qualifications and competencies for health, disabilities, and family services managers, as well as staff who work directly with children and families in the family partnership process. The qualification requirements represent minimum credentials we believe are critical to ensuring high-quality services. However, because we also recognize the important role of experience and community connections for such staff, these requirements are only for newly hired staff and, in some cases, give programs the flexibility to support staff in obtaining the credentials within 18 months of hire.

In response to public comments that the NPRM was not strong enough in addressing some serious public health issues, this final rule includes changes

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Findings from the Early Childhood Longitudinal Study, Kindergarten Class of 1998–99 (NCES 2004–078). U.S. Department of Education, National Center for Education Statistics. Washington, DC: U.S. Government Printing Office.

[27] Allington, R.L. & McGill-Franzen, A. (2003). The Impact of Summer Setback on the Reading Achievement Gap. *The Phi Delta Kappan, 85(1),* 68–75.; Fairchild, R. & Noam, G. (Eds.) (2007). *Summertime: Confronting Risks, Exploring Solutions.* San Francisco: Jossey-Bass/Wiley.

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[29] Benson, J., & Borman, G.D. (2010). Family, Neighborhood, and School Settings Across Seasons: When Do Socioeconomic Context and Racial Composition Matter for the Reading Achievement Growth of Young Children? *Teacher's College Record, 112*(5), 1338–1390.

[30] *Advisory Committee on Head Start Research and Evaluation: Final Report.* (2012). Washington, DC: Office of Head Start, Administration for Children and Families, U.S. Department of Health and Human Services.

[31] Curenton, S.M., Justice, L.M., Zucker, T.A., & McGinty, A.S. (2014). Language and literacy curriculum and instruction. Chapter 15 in in *Handbook of Response to Intervention in Early Childhood,* Buysee, V., & Peisner-Feinberg, E. (Eds.). Baltimore: Paul H. Brookes Publishing.

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[33] Justice, L.M., Mcginty, A., Cabell, S.Q., Kilday, C.R., Knighton, K., & Huffman, G. (2010). Language and literacy curriculum supplement for preschoolers who are academically at risk: A feasibility study. *Language, Speech, and Hearing Services in Schools, 41,* 161–178.

[34] Ginsburg, H.P., Ertle, B., & Presser, A.L. (2014). Math curriculum and instruction for young children. Chapter 16 in *Handbook of Response to Intervention in Early Childhood,* Buysee, V., & Peisner-Feinberg, E. (Eds.). Baltimore: Paul H. Brookes Publishing.

[35] Clements, D.H., & Sarama, J., (2008). Experimental evaluation of the effects of a research-based preschool mathematics curriculum. *American Educational Research Journal, 45*(2), 443–494.

that place a greater emphasis on certain health concerns, including childhood obesity prevention, health and developmental consequences of tobacco products and exposure to lead and support for mental health and social and emotional well-being. Given the prevalence of childhood obesity across the nation, especially among low-income children, we maintained important health and nutrition requirements and made specific changes to ensure Head Start actively engage in its prevention in the classroom and through the family partnership process. Given the serious health and developmental consequences of children's exposure to tobacco products, including second and third hand smoke, and to lead, we have explicitly required that programs offer parents opportunities to learn about these health risks and safety practices they can employ in their homes. We significantly strengthened the breadth and clarity on the requirements for programs to use mental health consultants to ensure Head Start programs are supporting children's mental health and social and emotional well-being. The final rule includes new provisions in the requirements for health, education, and family engagement services that elevate the role of Head Start programs in addressing these public health problems.

Additionally, through ongoing tribal consultations and the public comment process, we received important feedback from the American Indian and Alaska Native community. We made a number of changes specifically related to American Indian and Alaska Native programs based on these public comments and the unique and important sovereign relations with tribal governments. We added a new provision that for the first time makes it explicit that programs serving American Indian and Alaska Native children may integrate efforts to preserve, revitalize, restore, or maintain tribal language into their education services. We also clarified that, due to tribal sovereignty, American Indian and Alaska Native programs only need to consider whether or not they will participate in early childhood systems and activities in the state in which they operate.

In addition to these changes, the final rule maintains numerous changes proposed in the NPRM to strengthen program performance standards so all children and families receive high-quality services that will improve child outcomes and family well-being. We maintained and made important changes to strengthen service delivery. For example, we updated the prioritization criteria for selection and recruitment; made improvements to promote attendance; prohibited expulsion for challenging behaviors; strengthened services for children who are dual language learners (DLLs); and ensured critical supports for children experiencing homelessness or in foster care. Throughout the final rule we have made changes in response to public comments to make language clearer or more focused on outcomes rather than processes.

IV. Discussion of General Comments on the Final Rule

We received approximately 1,000 public comments on the NPRM with many commenters supporting our overall approach to revising the Head Start Program Performance Standards. Commenters appreciated our reorganization and streamlining, and agreed this made the standards more transparent and easier to understand. Commenters generally supported our approach to systems-based standards that are more focused on outcomes and less prescriptive and process-laden. They did note that how OHS monitored these standards would affect their implementation and impact. Commenters also appreciated our research-based approach. They noted our education and child development standards focused on the elements most important for supporting strong child outcomes. Commenters supported standards in the NPRM to improve services to children who are DLLs and their families. Commenters also supported our emphasis on reducing barriers and improving services to children experiencing homelessness and children in foster care. Overall, commenters agreed our proposal would improve program quality, clarify expectations, and reduce burden on programs.

We received a range of comments on our proposal to increase the minimum service duration for Head Start and Early Head Start programs. Some commenters supported the proposal to increase duration, citing the research base and its importance to achieving strong child outcomes. Many commenters stated that without sufficient funds, this would lead to a reduction in the number of children and families Head Start served and this would be an unacceptable outcome. Other commenters raised concern or opposition for a variety of other reasons. We discuss and respond to these concerns in detail our discussion of part 1302, subpart B.

Many commenters were concerned that the NPRM overall reflected a reduced commitment to the role of parents in Head Start. They also pointed to specific proposals in different subparts and sections, which they stated contributed to a diminished role for parents. It was not our intent to diminish the role of parents in the Head Start program, and we have revised provisions in the final rule to ensure our intent for parent engagement is appropriately conveyed. We believe parent engagement is foundational to Head Start and essential to achieving Head Start's mission to help children succeed in school and beyond. We address specific comments on parent involvement and engagement and our responses in the discussions of the relevant sections.

Many commenters believed there were excessive references to the Act. They asked that the final regulation translate the references to the Act with specific language or brief excerpts from the Act. We maintained the same approach as we proposed in the NPRM to reference the provisions in the Act so that the regulation will not become obsolete if the provisions in the Act change. However, we intend to issue a training and technical assistance document that integrates language from the Act into the same document as the program performance standards to address commenters' interest in having a single document.

We also received other general comments or comments not tied to a specific section or provision of the rule. For example, some commenters offered general support for the Head Start program and noted it was important for Head Start to continue. One commenter thought we should have included examples of excellent Head Start programs. Commenters stated their overall opposition to the Head Start program or the NPRM as a whole, and others did not want Head Start program to continue to receive funding. Commenters stated that services for DLLs were emphasized too heavily in the regulation or that the standards for DLLs were too prescriptive. We believe DLLs are an appropriate priority in the regulation because the provisions reflect requirements in the Act and because it is important programs effectively serve DLLs because they are a rapidly growing part of both Head Start and the broader United States population. Commenters also offered specific suggestions on ways to clarify, enhance, or add language relevant to serving culturally and linguistically diverse children and families, including children who are DLLs throughout the NPRM. We incorporated some of the suggestions into the final rule but felt some were already adequately covered while others were not feasible to include in regulation. We discuss these comments as appropriate in the relevant sections of the preamble.

Commenters also pointed out technical problems, such as incorrect cross references, typographical errors, or small inconsistencies in related provisions. We corrected these errors and made other needed technical changes, including edits to ensure descriptive titles throughout the final rule. Commenters also requested that we update existing data collections to account for changes in the program performance standards. As we make changes to the Head Start Program Information Report (PIR) and other data collections we sponsor, we will consider the final rule, but this is not a regulatory issue.

V. Discussion of Section by Section Comments on the Final Rule

We received many comments about changes we proposed to specific sections in the regulation. Below, we identify each section, summarize the comments, and respond to them accordingly.

Program Governance; Part 1301

This part describes program governance requirements for Head Start agencies. Program governance in Head Start refers to the formal structure in place "for the oversight of quality services for Head Start children and families and for making decisions related to program design and implementation" as outlined in section 642(c) of the Act. The Act requires this structure include a governing body and a policy council, or a policy committee at the delegate level. These groups have a critical role in oversight, design and implementation of Head Start and Early Head Start programs. The governing body is the entity legally and fiscally responsible for the program. The policy council is responsible for the direction of the program and must be made up primarily of parents of currently enrolled children. Parent involvement in program governance reflects the fundamental belief, present since the inception of Project Head Start in 1965, that parents must be involved in decision-making about the nature and operation of the program for Head Start to be successful in bringing about substantial change.[36]

We revised previous program governance requirements primarily to conform to the Act. We received many comments on part 1301. Below we discuss these comments and our rationale for any changes to the regulatory text in this subpart.

General Comments

Comment: Many commenters offered reactions to part 1301. Commenters expressed general support for the requirements, indicating they reflect the statutory requirements, improve transparency, maintain the important role of parents, and increase local flexibility.

Other commenters stated this part was unnecessarily complicated for parents, policy council members, and staff to follow as presented in the NPRM. Many commenters suggested all governance requirements be clearly stated in the rule rather than referenced with statutory citation in order to improve clarity and reduce burden for programs, parents, and others.

Response: As noted previously, we maintained the approach to cross reference to the Act so that the regulations will not become obsolete if the provisions in the Act change. However, we plan to issue a training and technical assistance document that incorporates the language from the Act with the regulatory language.

Comment: Some commenters suggested we failed to address the role of shared governance in the Head Start program, and that we relied too heavily on the Act, which is vague and ambiguous, and leaves grantees wondering about the proper balance between the role and responsibility of the governing body and the policy council. These commenters ask that we include more specificity about shared governance in the final rule.

Response: We continue to believe the best approach is to align the governance requirements in the rule with the language and requirements specified in the Act. The statutory language has directed the governance of Head Start programs since it was passed in 2007 and there have not been any significant problems with this approach.

Comment: Commenters asked that we include "Tribal Council" wherever the phrase "governing body" occurs.

Response: We do not believe this is necessary, since the tribal council is acting as the governing body.

Section 1301.1 Purpose

This section reiterates the requirement in section 642(c) of the Act regarding the structure and purpose of program governance. The structure as outlined in the Act includes a governing body, a policy council, and, for a delegate agency, a policy committee. We restored the requirement from the previous performance standards that programs also have parent committees as part of the governance structure, and we discuss this requirement in more detail in § 1301.4. This section emphasizes that the governing body has legal and fiscal responsibility to administer and oversee the program, and the policy council is responsible for the direction of the program including program design and operations and long- and short-term planning goals and objectives.

Comment: Commenters recommended that we revise the language in this section to state clearly that each agency must establish a policy council.

Response: We proposed in the NPRM to use the term "policy group" to encompass the policy council and the policy committee more concisely. We defined "policy group" to mean "the policy council and policy committee at the delegate level." After further consideration and in response to comments, we reverted to using "policy council and policy committee at the delegate level." It is lengthier but clearer. Instead of introducing a new term, we are remaining consistent with the Act.

Comment: Some commenters raised concerns with the policy council being responsible for the direction of the Head Start program. Commenters stated it was unclear how the policy council could be effective in that role. Others said both the governing body and the policy council should be responsible for the direction of the program or that this responsibility should rest solely with the governing body.

Response: We maintained the language proposed in the NPRM because it is the statutory requirement in the Act that the policy council is responsible for the direction of the Head Start and Early Head Start programs.

Section 1301.2 Governing Body

In the NPRM, this section described training requirements; however, we moved training requirements to § 1301.5 and this section now pertains to the governing body.

This section includes requirements for the composition of the governing body and its duties and responsibilities. It aligns with the Act's detailed requirements for the composition and responsibilities of the governing body. This section requires governing body members use ongoing monitoring results, data from school readiness goals, the information specified in section 642(d)(2) of the Act, and the information in § 1302.102 to conduct their responsibilities. Paragraph (c) permits a governing body, at its own discretion, to establish advisory committees to oversee key responsibilities related to program governance, consistent with section 642(c)(1)(E)(iv)(XI) of the Act. Below we address comments and requests for clarification.

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[36] *See* **Federal Register**, 40 FR 27562, June 30, 1975.

Comment: We received some comments on the governing body's duties and responsibilities that addressed the duties and responsibilities of both the governing body and the policy council together. Some commenters requested we provide a clear illustration of the responsibilities and powers of the governing body and policy council by including a chart or diagram. Commenters also provided specific suggestions for revisions, such as: Add language from the previous performance standards on the duties and responsibilities of the governing body and policy council; remove language specific to ongoing monitoring and school readiness goals, as this is addressed in another section; and require that program goals inform the governing body and policy council.

Response: We did not include a diagram or chart in this rule because we believe the governance provisions in the rule and in the Act are clear. In response to comments, we added to paragraph (b)(2) a cross-reference to the requirement in § 1302.102 related to establishing and achieving program goals. By adding this cross reference, we are requiring governing bodies to use this information to conduct their responsibilities.

Comment: Some commenters offered support and raised concerns about the governing body's duties and responsibilities as laid out in paragraph (b). Some commenters supported the requirement that the governing body use ongoing monitoring results and school readiness goals to conducts it responsibilities, in addition to what is required in section 642(d)(2) of the Act. Some commenters suggested we enhance or clarify language about when programs needed to report to the responsible HHS official. Commenters also requested clarification about the governing body's responsibility to establish, adopt, and update Standards of Conduct, including reporting any violations to the regional office and about self-reporting requirements for immediate deficiencies.

Response: The Act specifies that the governing body is responsible for establishing, adopting, and periodically updating written standards of conduct, so we believe this is addressed because we incorporated this requirement from the Act. We revised § 1302.90(a) to clarify the role of the governing body in standards of conduct, which we had inadvertently left out of that standard. We did not revise the requirement about self-reporting because it is addressed in § 1302.102.

Comment: Many commenters stated the proposed rule was unclear about conflicts of interest. Commenters requested clarification about this provision and recommended adding language that mirrors the IRS Form 1023 Instructions, Appendix A, Sample Conflicts of Interest Policy.

Response: We did not make changes to this language. There is guidance in the nonprofit community about the various ways to structure and apply a conflict of interest policy. If an agency wants to adopt the IRS rules, that would be one option, but it might not be the right option for all programs. Additionally, the governing body is required to develop a written conflict of interest policy, which can provide greater clarity than the overarching federal requirements.

Comment: We received comments on advisory committees described in paragraph (c). Some commenters requested additional clarification, including who the advisory board is and what groups should be included and whether the governing body may establish more than one advisory committee. Others commenters suggested revisions to the advisory committee's role advisory committee with respect to the governing body. For example, commenters stated that all areas of program governance, especially supervision of program management, should be left in the hands of the Board of Directors or the established governing body. Some commenters noted that advisory committees should not make decisions about program governance because that is not advisory in nature. Other commenters made specific suggestions for the language related to advisory committees, such as eliminating the composition requirements, eliminating the requirement that advisory committees be established in writing, and differentiating between advisory committees that act as sub-boards versus other advisory committees.

Response: To improve clarity, we revised and streamlined paragraph (c). We clarified that governing bodies may establish one or more advisory committees. We removed some of the more prescriptive requirements, such as written procedures or composition requirements, and explicitly required that when the advisory committee is overseeing key responsibilities related to program governance, it is the responsibility of the governing body to establish the structure, communication and oversight in a way that assures the governing body retains its legal and fiscal responsibility for the Head Start agency. This allows the governing body flexibility to structure their advisory committee but requires that they retain legal and fiscal responsibility for the Head Start agency. We also require the governing body to notify the responsible HHS official of its intent to establish such an advisory committee.

Section 1301.3 Policy Council and Policy Committee

In this section, we retain a number of requirements from the previous program standards and included requirements to conform to the Act. In paragraph (a), we retain the requirement for agencies to establish and maintain a policy council at the agency level and a policy committee at the delegate level, consistent with section 642(c)(2) and (3) of the Act. Paragraph (b) outlines the composition of policy councils, and policy committees at the delegate level, consistent with the Act. Paragraph (c) outlines the duties and responsibilities for the policy council and the policy committee to conform to the Act and is largely unchanged from the NPRM. Paragraph (d) addresses the term of service for policy council and policy committee members.

Comment: Commenters recommended we include all of the statutory language from section 642(c)(2)(A) of the Act in this section, rather than summarizing that the policy council has responsibility for the direction of the program. Another recommended the policy committee at the delegate level be renamed to "Policy Action Committee" to eliminate programs from using "PC" for both policy council and policy committee.

Response: We did not revise the concise reference to the policy council having responsibility for the direction of the program, although the Act's more expansive language is still part of the requirement. We maintain the terminology as it exists in the Act and did not rename "policy committee" at the delegate level.

Comment: Commenters supported the standard in paragraph (b) to require proportional representation on the policy council by program option but also recommended revisions and asked for additional clarification. For example, commenters requested clarification on what proportional representation means and how to implement it within different program types.

Other commenters expressed support for the requirement that the majority of policy council members be parents but requested that language be added to the rule, rather than just citing the Act. Others requested clarification on how appropriate composition will be maintained and consistent with the Act when parents drop out.

Response: We revised paragraph (b) to clarify that parents of children currently enrolled in "each" program option must be proportionately represented on the policy council or the policy committee. We believe programs should have the flexibility to specify in their policies and procedures how the composition requirements will be maintained when parents drop out and did not make revisions to address this.

Comment: Commenters expressed disagreement with language in the preamble to the NPRM stating, "We propose to remove current § 1304.50(b)(6) which excludes staff from serving on policy councils or policy committees with some exceptions. . .". Commenters expressed confusion and stated this language has been interpreted to mean staff would be allowed to participate as a policy council or policy committee member. Though one commenter expressed support for allowing staff to serve on the policy council because they have field experience and skills to make informed decision, the commenters generally stated it is a conflict of interest and could inhibit parent driven decision-making.

Response: In the NPRM, we proposed to remove § 1304.50(b)(6), which excludes staff from serving on policy councils or policy committees with some exceptions, because it is superseded by the Act. In other words, the conflict of interest language in the Act, as well as the Act's clarity on who can serve on the policy council, means we no longer need the prohibition on staff serving on policy council or policy committee. However, commenters noted the exception related to substitute teachers is helpful and clarifying for programs. Therefore, we added the majority of the language on this topic from the previous performance standards back into paragraph (b)(2) to ensure clarity.

Comment: Commenters stated the Act gives the policy council responsibilities outside its scope of authority, and that the final rule should be modified to include language from the previous regulation related to duties and responsibilities. Commenters recommended we instead should focus the responsibilities of the policy council on program issues.

Response: In the final rule, we maintained the alignment with the Act with respect to the duties and responsibilities of the policy council. We did not add the requested language from the previous regulation because it has been superseded by the Act.

Comment: Some commenters requested that we clarify in the final rule the role of the policy council in hiring and terminating staff.

Response: We did not include a specific provision on the role of policy council in hiring and terminating program staff because we rely on the language in section 642(c)(2)(D)(vi) of the Act.

Comment: Many commenters supported allowing programs to establish in their bylaws five one-year terms for policy council members as opposed to three. Commenters said the change would support continuity, increase understanding of the complexities of the Head Start program and regulation, and promote investment in the policy council.

Some commenters opposed the option of extending policy council terms from three one-year terms to five. They stated that five years is too long, that parents may not have children in the program for five years, and that a shorter term would allow for more new members.

Response: We did not revise this provision. This rule provides programs the discretion to establish in their bylaws the number of one-year terms of policy council members up to five one-year terms. Programs have the discretion of setting a lower limit.

Comment: We received comments about the term "reasonable expenses" in paragraph (e). Commenters recommended we add a definition of "reasonable expenses," allow that all participants on the policy council/committee be reimbursed for "reasonable expenses," and allow agencies to develop their own policies and procedures to determine eligibility based on the need of their communities.

Response: We did not clarify the definition of "reasonable" but allow programs to make a determination. We clarified that eligibility for the reimbursement is only for low-income members.

Section 1301.4 Parent Committees

Comment: We received many comments about our proposal to remove the requirement for the parent committee. Some commenters supported the proposal to remove the parent committee requirement. They emphasized that there are more meaningful and inclusive ways to engage parents that could allow for individual program flexibility and innovation. These commenters suggested that the focus should instead be on providing opportunities for parents to learn about their children and engage them in teaching and learning and on family engagement outcomes.

Some commenters supported the removal of the parent committee requirement with reservations, but were concerned about the challenges it would pose for electing policy council representatives, about the loss of the benefits to parents previously derived from participation in parent committees, and about the perceived erosion of a core philosophy of Head Start. Others asked that the revised requirement ensure a structure for representing parent views and offering parents other opportunities for engagement.

Many commenters opposed the removal of parent committees. Commenters urged that we reinstate the parent committee requirement as it existed in the previous standards. These commenters stressed that parents are foundational to Head Start and that parent committees are a long-standing cornerstone of the program. They stated removing the requirement for parent committees would weaken Head Start parent engagement and diminish parents' role. Commenters noted that parent committees stimulate parent participation in the program, help parents develop leadership, advocacy and other useful skills, and are critical to developing membership for policy council. Commenters disagreed with our statement in the NPRM that parent committees do not work in all models, such as Early Head Start—Child Care Partnership (EHS–CCP) grantees, and suggested we help these grantees learn how to incorporate this valuable experience for parents in order to infuse a higher level of quality into child care settings. Commenters were also concerned that the removal of parent committee would result in the loss of in-kind contributions from parent involvement.

Some commenters opposed the removal of the parent committee requirement and asked that we make modifications or recommended alternative language in the final rule if the parent committee requirement is removed. These commenters stated similar concerns to those who requested that we reinstate the requirement, but made suggestions for the final rule, such as to allow individual programs to determine the design and structure of parent committees, or to support flexibility in local design of parent committees and proposals for alternate mechanisms to engage families. Some of these commenters believed that parent committees are not for all parents. These commenters asked that programs be required to have a process in place that ensures all parents of enrolled children have local site opportunities to actively share their ideas, that parents understand the process for elections or nominations to serve on the policy council, and that a communication system exist to share information between parents attending local sites and the policy council and governing body.

Response: We restored a requirement for a parent committee in this part and in a new § 1301.4. We also note that a parent committee is part of the formal governance structure in § 1301.1. This section clearly outlines the requirements for a program in establishing a parent committee and the minimum requirements for parent committees, which are consistent with all of the substantive requirements from the previous performance standards. We maintain the requirement that a program must establish a parent committee comprised exclusively of parents of currently enrolled children as early in the program year as possible and that the parent committee must be at the center level for center-based programs and at the local program level for other program options. In addition, in response to comments, we require programs to ensure parents of currently enrolled children understand the process for elections to policy council or policy committee or other leadership roles. Also as suggested by commenters, we allow programs flexibility within the structure of parent committees to determine the best methods and strategies to engage families that are most effective in their communities as long as the parent committee carries out specific minimum responsibilities. It requires that parent committees (1) advise staff in developing and implementing local program policies, activities, and services to ensure they meet the needs of children and families, and (2) participate in the recruitment and screening of Early Head Start and Head Start employees, both of which are retained from the previous performance standards. In response to comments we have added a requirement that the parent committee have a process for communication with the policy council and policy committee at the delegate level.

Section 1301.5 Training

This section describes the training requirements for the governing body, advisory committee members, and the policy council. It reflects section 642(d)(3) of the Act that requires governing body and policy council members to have appropriate training and technical assistance to ensure they understand the information they received and can oversee and participate in the agency's programs effectively. We moved this section from § 1301.2 in the NPRM to this placement in the final rule to improve overall clarity of part 1301. We discuss comments and our responses below.

Comment: We received comments that requested clarification or suggested ways to improve clarity. We also received comments that expressed opposition for the requirement. For example, commenters requested clarification on what is considered "appropriate" training and what is included in training. One commenter requested clarification on the inclusion of advisory committee members in the training. Commenters recommended we move this section out of § 1301.2, and others recommended we improve clarity by cross-referencing training requirements in another section. Some commenters opposed our requirement that governing bodies be trained on the standards because they thought it was unrealistic to expect Boards to have knowledge of all the operating standards and it detracted from getting input from governing bodies on program outcomes.

Response: We retained this requirement because it is required by the Act and because we believe governing bodies cannot effectively fulfill their program management responsibilities unless they have an understanding of the broader program requirements. Since governing bodies can choose to establish advisory committees, we included advisory committee members, who may be different individuals than governing body members, in this requirement.

To improve clarity, we moved these standards from § 1301.2 to this section so that it follows sections with the requirements for all components of an agency's formal governance structure. We revised the section to include a cross reference to training requirements in § 1302.12.

Section 1301.6 Impasse Procedures

This section on impasse procedures was found in § 1301.5 in the NPRM and is now § 1301.6 in the final rule. It describes procedural requirements for resolving disputes between an agency's governing body and policy council. We received many comments on our proposed impasse procedures. Many commenters believed our proposed impasse procedures weakened the role of parents in the Head Start program. They stated that we relegated the policy council, the majority of which is comprised of parents, to an advisory role by allowing the governing body the final decision when an impasse remained unresolved. In response to comments, we revised the impasse procedures. A discussion of the comments and our response is below.

Comment: Many commenters opposed our proposal for the dispute resolution and impasse procedures. Commenters stated our impasse procedure proposal contributed to a broader weakening of the role of parents in Head Start because it tilted the power balance toward the governing body and away from the policy council. They also stated that the standards conflicted with other program performance standards in this section and requirements in the Act. For example, they stated the proposal conflicted with the requirement for "meaningful consultation and collaboration about decisions of the governing body and policy council." Commenters stated that conflicts often result from issues related to the direction of the program, which is the responsibility of the policy council. These commenters suggested that the proposed requirements amount to capitulation to the will of the governing body and are not actually impasse procedures, in contradiction with the Act's requirement. Others commenters noted further contradiction given the standards would require the governing body and policy council to work together yet exclude the policy council and allow the governing body to make the final decision. Some commenters stated that they embrace shared governance and provided examples of how the voice of parents has been critical to their decision-making during, for example, sequestration or previous impasses. Commenters made recommendations, such as adding formal mediation, strengthening the language related to "meaningful consultation and collaboration about decisions of the governing body and the policy council," referring to the impasse procedures as a consensus-building process, and establishing an independent arbitrator or third party to resolve disputes between the governing body and policy council.

We also received comments supporting the impasse procedures proposed in the NPRM. Some of these commenters stated that it is appropriate for the governing body, since they bear legal and fiscal responsibility, to make the ultimate decisions on issues related to the Head Start program after taking into consideration the recommendations of the policy council and policy committee, if applicable. Further, commenters asked for additional clarification about our proposed requirements, including the timeline for resolution.

Response: For clarity, we included the statutory language that requires "meaningful consultation and collaboration about decisions of the governing body and policy council," and we maintained requirements from the previous performance standards about these bodies jointly establishing written procedures for resolving internal disputes. We revised the requirements in this section to clarify the role of policy councils in the governance of Head Start programs, including processes to resolve conflicts with the governing body in a timely manner, and we included more specificity about what impasse procedures must include in order to better articulate the balanced process. In paragraph (b), we included a new standard that requires that in the event the decision-making process does not result in a resolution of the impasse, the governing body and policy council must select a mutually agreeable third party mediator and participate in a formal process that leads to a resolution. In paragraph (c), we require the governing body and policy council to select a mutually agreeable arbitrator, whose decision will be final, if no resolution resulted from mediation. Due to tribal sovereignty, we excluded American Indian and Alaska Native programs from the requirement in paragraph (c) to use an arbitrator.

Program Operations; Part 1302

Overview

In § 1302.1, we made a technical change to remove paragraph (a) because the content of this paragraph was already included in the statutory authority for this rule and for this part and is therefore unnecessary to repeat here. Therefore what was paragraph (b) in the NPRM is an undesignated paragraph in the final rule.

Eligibility, Recruitment. Selection, Enrollment and Attendance; Subpart A

In this subpart, we combined all previous requirements related to child and family eligibility, and program requirements for the recruitment, selection, and enrollment of eligible families. We updated these standards to reflect new priorities in the Act, including a stronger focus on children experiencing homelessness and children in foster care. We added new standards to reflect the importance of attendance for achieving strong child outcomes. Further, we included new standards to clarify requirements for children with persistent and disruptive behavioral issues as well as new standards to support programs serving children from diverse economic backgrounds, when appropriate. Commenters supported our reorganization of these requirements and our emphasis on special populations. Commenters were particularly appreciative of the standards throughout the section that were designed to reduce barriers to the participation of children experiencing homelessness. We made technical changes for improved clarity. We discuss additional comments and our responses below.

General Comments

Comment: Commenters recommended adding language that specifically encouraged the recruitment and enrollment of children who are culturally and linguistically diverse, and/or prioritizing linguistically diverse children for enrollment.

Response: We do not think it is necessary to explicitly encourage recruitment or prioritization of culturally and linguistically diverse children. Twenty-nine percent of Head Start children come from homes where a language other than English is the primary language.[37] Additionally, as described in § 1302.11(b)(1)(i), the community assessment requires programs to examine the eligible population in their service area, including race, ethnicity, and languages spoken. A program must then use this information when it establishes selection criteria and prioritization of participants, as described in § 1302.14(a)(1).

Section 1302.10 Purpose

This section provides a general overview of the content in this subpart. We received no comments directly for this section but made changes to be consistent with revisions in § 1302.11.

Section 1302.11 Determining Community Strengths, Needs, and Resources

This section includes the requirements for how programs define a service area for their grant application and the requirements for a community assessment. We streamlined the standards to improve clarity and reduce bureaucracy. In addition, we eliminated a prohibition on overlapping service areas, added new data as required by the Act for consideration in the community assessment to ensure community needs are met, and aligned the community assessment to a program's five-year grant cycle. We also required that programs consider whether they could serve children from diverse economic backgrounds in addition to the program's eligible funded enrollment in order to support mixed-income service delivery, which research suggests benefits children's early learning.[38] [39] Below, we summarize and respond to the comments we received.

Comment: Many commenters opposed or expressed concern about our proposal to eliminate the prohibition on overlapping service areas. For example, commenters stated that overlapping service areas will be confusing and will cause conflict because of competition between grantees. Many commenters suggested we include a process for mediation when there are disputes. Commenters supported our decision to remove the prohibition on overlapping service areas.

Response: We believe removing the prohibition on overlapping service areas gives greater flexibility to local programs in a manner that will benefit the children and families they serve. Grantees may request additional guidance through the system of training and technical assistance. Therefore, we did not reinstate the prohibition on overlapping service areas in this rule.

Comment: We received a few different recommendations for additional criteria for defining service area. For example, many commenters recommended we include parents' job locations as part of the service area.

Response: While the service area is based on children's residence, this rule, as well as the previous regulation, is silent on whether a program can enroll a child that lives outside of the service area if their parents work in that area. We believe programs already have the flexibility to determine whether a child should be enrolled at a program closer to a parent's workplace and will clarify any existing sub-regulatory guidance to reflect this flexibility. We made no changes to this provision.

Comment: We received suggestions for paragraph (b)(1) to more explicitly address the purpose and the goal of the community needs assessment, to add additional or change criteria to the data (either on the five-year cycle or annually), and to provide more guidance on how programs should obtain data for the community needs assessment.

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[37] U.S. Department of Health and Human Services, Administration for Children and Families (2015). *Office of Head Start Program Information Report, 2014–2015*. Washington, DC: Author.

[38] Mashburn, A.J., Justice, L., M., Downer, J.T., & Pianta, R.C. (2009). Peer effects on children's language achievement during pre-kindergarten. *Child Development, 80*(3), 686–702.

[39] Henry, G.T., & Rickman, D.K., (2007). Do peers influence children's skill development in preschool? *Economics of Education Review, 26*(1), 100–112.

Response: We made changes to the section title and clarified that the community assessment should be strengths-based. We think these changes, together with using the full name of the community assessment—"community wide strategic planning and needs assessment"—better reflect the purpose of the assessment. We revised paragraph (b)(1) to clarify that this list is not exhaustive, and reorganized the list to make it more logically flow. We also revised paragraph (b)(1)(ii) to also include prevalent social or economic factors that impact their well-being. We did not believe additional data requirements were necessary because programs already have the flexibility to include other relevant data in their community assessments. We clarified in paragraph (b)(1)(ii) that homelessness data should be obtained in collaboration with McKinney-Vento liaisons to the extent possible, but it is important that all programs consider the prevalence of homelessness in their community, however possible. The U.S. Interagency Council on Homelessness has identified data gaps in tribal communities on young children experiencing homelessness, so we recognize tribal programs may need to utilize alternative methods to ensure they fully consider the prevalence of homelessness in their communities.

Comment: We received comments about our proposal in paragraph (b)(1) to change the community assessment from a three-year to a five-year timeline that would align with a program's five-year grant cycle. Some commenters supported this change because it removed unnecessary burden on programs. Commenters expressed concern that communities change rapidly and that five years is not frequent enough to review community needs.

Response: We think we strike the right balance between ensuring programs regularly assess and work to meet their community needs through an annual re-evaluation of particular criteria described in paragraph (b)(2) and § 1302.20(a)(2) and reduction of undue burden through alignment of the community assessment to the five-year grant cycle. We made no revisions to this timeline.

Comment: Many commenters recommended we change the requirement in paragraph (b)(2) that programs must annually review and update the community assessment to reflect any significant changes to the availability of publicly-funded full-day pre-kindergarten. These commenters expressed concern that public pre-kindergarten programs may not meet the needs of at-risk families because they do not offer a full spectrum of comprehensive services. Commenters offered specific suggestions for other community demographics to be considered in the annual review.

Response: Since the requirement to conduct community assessments was changed from every three years to every five years, this provision was intended to ensure programs annually capture what may be quickly changing demographic and policy landscape characteristics in their community. Emergence or expansion of publicly funded pre-kindergarten may offer new opportunities for partnerships and collaborations or it may offer new opportunities to extend the hours children receive services. We retained the standard that programs review and update the annual assessment to reflect any increase in the availability of publicly-funded pre-kindergarten including but not limited to "full-day" programs. In addition, we clarify that this review and update should take into account whether the pre-kindergarten available meets the needs of the population of the grantee serves. We revised paragraph (b)(2) to also include significant shifts in community resources, because community demographics was too narrow.

Comment: We received some comments in support of our proposed standard in paragraph (b)(3) for programs to consider whether characteristics of the community allow them to operate classes with children from diverse economic backgrounds. These commenters noted research demonstrates participation in mixed-income classes is beneficial to children from low-income families and stated the standard would support a broader notion of innovative funding models. We also received many comments requesting additional guidance to ensure this standard did not result in fewer services for income eligible children.

Response: The intent of this requirement is for Head Start programs to consider whether it is feasible to implement a mixed-income delivery model. Research finds such models to be beneficial to the educational outcomes of children from low-income families.[40] [41] However, we revised this paragraph to clarify programs must not enroll children from diverse economic backgrounds if it would result in them serving less than their eligible funded enrollment. In addition, to both support consideration of innovative funding models and clarify our intent that children funded through other sources must not receive services instead of children eligible for Head Start, we revised paragraph (b)(3), and §§ 1302.15(d) and 1302.18(b)(2).

Section 1302.12 Determining, Verifying, and Documenting Eligibility

This section includes the process for programs to determine, verify, and document child and family eligibility for Head Start programs. We reorganized these requirements to clarify and better reflect best practices in the field. We also made technical and structural changes to standards that caused confusion in the field after publication in February 2015 of the final rule on eligibility, to eliminate duplication, and to update terms such as replacing "land-base" with "service area."

Comment: Commenters suggested changes to paragraph (a), which provides an overview of the process to determine, verify, and document eligibility. Suggestions included a recommendation to delineate more specific conditions under which alternative methods for eligibility determination would be approved and when in-person interviews would always be required.

Response: We made one revision to paragraph (a). We noted that telephone interviews could be permitted when it was more convenient for the family and eliminated the need to document the reason. Otherwise we made no revisions as we think paragraph (a)(3) is broad enough to provide flexibility and encourage innovation at the local level.

Comment: Many commenters expressed concern about the age provisions in paragraph (b). For example, some supported children transitioning to Head Start as soon as they turn three years old, whereas others suggested children stay in Early Head Start until the next program year. Others suggested that transitions should be based on developmental needs rather than birthdays. Many commenters were concerned about how the standards in this paragraph and paragraph (j) interacted with the allocation of funds for Early Head Start-Child Care Partnerships (EHS–CC Partnerships). Specifically, commenters were concerned that EHS–CC Partnerships can serve children up to 48 months of age for family child care, and paragraph (b)(1) states a "child must be an infant or a toddler younger than three years old."

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[40] Mashburn, A.J., Justice, L.M., Downer, J.T., & Pianta, R.C. (2009). Peer effects on children's language achievement during pre-kindergarten. *Child Development, 80*(3), 686–702.

[41] Henry, G.T., & Rickman, D.K. (2007). Do peers influence children's skill development in preschool? *Economics of Education Review, 26*(1), 100–112.

Response: The ages children are eligible for Early Head Start are defined by the Act and not subject to regulatory change. The rule sets forth reasonable flexibility for transitioning children to Head Start or other early learning programs when they turn three years of age. Additional standards for this transition are in subpart G. Thus, we made no changes to provisions in this section regarding children turning three years of age. Further, the EHS–CC Partnerships appropriation explicitly allowed serving children up to 48 months old for family child care, which supersedes regulatory language.

Comment: Commenters noted Head Start eligibility in paragraph (b) should not be tied to compulsory school attendance because in some states that would mean Head Start would have to serve children up to age six or seven.

Response: It is clear from program data that standard practice is that Head Start programs serve children until they are eligible for kindergarten. However, the Act explicitly references eligibility up to compulsory school age. In addition, we think the final rule allows flexibility in the very rare circumstances it is needed. We made no revisions to these provisions.

Comment: We received many comments on eligibility requirements in paragraphs (c), (d), (e), (f), and (g). For example, commenters recommended changes for income eligibility, continuous eligibility between Early Head Start and Head Start programs, new groups for categorical eligibility, and flexibility to reallocate funds at program discretion between Early Head Start and Head Start programs. Commenters also recommended changes in paragraph (j) of this section to address continuous eligibility. Commenters recommended we change prioritization requirements. Commenters also requested additional clarification for some of the proposed criteria, including on the definition of public assistance and absence of child care.

Response: Most suggestions for amendments to eligibility would require legislative action by Congress and cannot be changed through regulation. For other suggestions, we want to allow local programs the flexibility in their selection process to determine which children and families are most in need. Therefore, we made no revisions to income eligibility, groups for categorical eligibility, or prioritization requirements. We made technical changes in this section to clarify that categorical eligibility is not a separate term used for eligibility. In addition, we made changes in paragraph (c)(1)(ii) to clarify that families are eligible if the child is receiving a Temporary Assistance for Needy Families (TANF) child-only payment. Finally we made technical changes in paragraph (d)(1) to correct the wording that implied individuals were ineligible at 100–130% of poverty. Programs may request additional guidance through the system of training and technical assistance.

Comment: Commenters recommended modifying standards to allow programs to participate in a community wide and/or statewide recruitment and intake processes.

Response: Programs already have the flexibility to participate in such systems and are expected to collaborate with community partners to ensure they are serving the children most in need. No revisions were made regarding this issue.

Comment: We received some comments about verification standards for public assistance described in paragraph (i). Some commenters supported the standards, noting they would ensure uniform practices across programs. Others opposed them or expressed concerns, with some stating they would be costly, and would delay enrollment. Commenters requested additional clarification for standards in this paragraph, including what was meant by "all" tax forms.

Response: We agree that the verification standards for public assistance will ensure uniform practices across programs and believe this is important to program integrity even if it may cause some delays, so we have not changed this language. We added language to the standard in paragraph (i)(1)(i) to include proof of income from individuals who are self-employed. This is meant to clarify that income sources from informal work, such as day laborers, should be included for income eligibility. Additionally we removed "all" before tax forms. We realize that programs want to be conscientious about proper eligibility verification so we will continue to provide guidance and support about the implementation of these standards as requested.

Comment: As noted previously, some commenters submitted suggestions about eligibility duration standards in paragraph (j). Some commenters recommended changes that would facilitate eligibility from Early Head Start to Head Start. Commenters noted that the standard in paragraph (j)(4) can complicate a program's enrollment of over-income slots if an eligible family becomes more self-sufficient during their time in Head Start.

Response: The Act sets forth the requirements for the re-determination of eligibility for Head Start after Early Head Start so we do not have authority to change these standards. We believe programs have enough flexibility in their prioritization criteria in paragraph (j)(4), so we did not make changes.

Comment: Commenters requested clarification of the standards in paragraph (m) about eligibility training. For example, commenters were confused by outdated language in paragraph (m)(3).

Response: To improve clarity of this paragraph, technical changes were made to eliminate language in paragraph (m)(3), which was unnecessary and confusing because it noted an outdated timeline tied to the final eligibility rule published in February 2015.

Section 1302.13 Recruitment of Children

This section maintained and streamlined standards from the previous rule about the goal of recruitment efforts and some specific efforts a program must make.

Comment: We received some comments on this section, including requests for clarification and recommendations for additional emphasis on recruitment of certain populations.

Response: Programs are required to serve children with disabilities as at least 10 percent of their funded enrollment. Therefore, requiring active recruitment for this specific population is appropriate. We added that programs should also actively recruit other vulnerable populations, including homeless children and children in foster care, and provided programs with the flexibility to define these populations based on their community assessment.

Section 1302.14 Selection Process

This section describes the selection process and specific criteria programs must use to weigh the selection of eligible children. It includes a new requirement for programs to prioritize serving younger children if they operate in a service area with high-quality publicly funded pre-kindergarten. This section also included standards to conform with provisions from the Act that require at least 10 percent of a program's total enrollment to be children eligible for services under the Individuals with Disabilities Education Act (IDEA). Commenters appreciated the emphasis on a priority for children experiencing homelessness and children in foster care. We address these and other suggestions below.

Comment: For a number of reasons, many commenters opposed the standard in paragraph (a)(3) that would require programs to prioritize serving younger children if publicly-funded pre-kindergarten is available for a full school day. For example, commenters were concerned this requirement would limit families with 4-year-olds from receiving the full range of comprehensive services and supports offered by Head Start. They were also concerned it would interfere with or even unravel partnerships with publicly-funded pre-kindergarten programs. Some commenters stated this provision interfered with tribal sovereignty. Some commenters supported greater priority for younger children and some recommended we include additional standards to further this goal. Commenters also recommended that American Indian and Alaska Native programs be exempt from this requirement.

Response: We have maintained this requirement because we believe programs should be serving more 3-year-olds and infants and toddlers in areas where there is high-quality, accessible pre-kindergarten for 4-year-olds. We revised this standard to reflect that the high-quality publicly funded pre-kindergarten must be accessible for the requirement to apply and clarified that this priority is part of the selection criteria programs establish as described in paragraph (a)(1). This, for example, would give programs flexibility to weigh other criteria that would not disrupt programs serving siblings or a child with a disability if it was determined this was the best placement. We also clarified that this prioritization would not be required if it interfered with partnerships with local educational agencies. Finally, we revised this requirement to clarify that American Indian and Alaska Native and Migrant and Seasonal Head Start programs must only consider this prioritization.

Comment: We received some comments about the requirement in paragraph (b) for 10 percent of a program's funded enrollment to be composed of children eligible for services under IDEA. Some commenters supported this standard. Some commenters stated it was a difficult standard to meet in rural communities, and others recommended it be calculated across a grantee's Early Head Start and Head Start enrollment. Some commenters requested additional clarification, and some commenters requested we add specific criteria for the waiver for this standard and requested children with disabilities be given the first priority on any waiting list until the 10 percent requirement is met.

Response: This standard is required by the Act. Therefore, we cannot revise its calculation. We slightly revised the language in paragraph (b)(1) to better clarify the 10 percent is calculated from a program's total funded enrollment. Our current waiver process evaluates whether programs are making reasonable efforts to comply with the 10 percent requirement. Nationally, more than 12 percent of Head Start enrollment is comprised of children with disabilities, so we do not believe a change is necessary.[42]

Comment: Some commenters recommended changes to waiting list requirements in paragraph (c). Some recommended less focus on a waitlist and some recommended more focus and specificity.

Response: We believe the standard in paragraph (c) is appropriate to ensure any openings during the program year get filled promptly. We made no revisions.

Section 1302.15 Enrollment

This section reorganized and revised previous standards about enrollment. It includes requirements about how quickly programs must fill vacancies and efforts they must undertake to maintain enrollment of eligible children for subsequent years. It includes standards to reduce barriers to enroll children experiencing homelessness. This section includes new standards about reserving slots for pregnant women, children experiencing homelessness, and children in foster care. This section also includes a new standard to allow the enrollment of children who are funded through non-Head Start sources, including private pay. Further, this section includes a standard that clarified current policy that required programs to follow their state immunization enrollment and attendance requirements. We moved the standard from § 1302.17(c) in the NPRM to paragraph (f) to improve clarity. We received many comments on this section, which we discuss below.

Comment: We received comments opposed to our proposal in paragraph (a) that programs must fill any vacancy within 30 days because the previous performance standards did not require programs to fill a vacancy within 60 days of the end of the program year. Commenters expressed a variety of reasons for their opposition, such as difficulty meeting all of the comprehensive service requirements in the allotted time period.

Response: We retained this provision with minor technical changes because we believe the provision of comprehensive services is beneficial to children—even during a period of 60 days or less. In addition, in some programs, 60 days represents one-quarter of the program year and allowing such a long period of vacancy represents lost opportunity and wasted funds. Furthermore, enrollment within the last 60 days of the program year will facilitate service delivery for the following program year.

Comment: We received comments that the standard proposed on eligibility duration that appeared in paragraph (b)(2) of the NPRM was redundant and unnecessary because of standards in § 1302.12(j)(2) and (3).

Response: We agree and have struck the provision that was paragraph (b)(2) in the NPRM.

Comment: We received many comments recommending changes to the standard in paragraph (b)(2) (formerly paragraph (b)(3) of the NPRM) that allows a program to maintain a child's enrollment for a third year under exceptional circumstances as long as family income is re-verified. For example, some commenters recommended we strike this provision because it was inconsistent with § 1302.12(b)(2) and the Act. Other commenters requested we define "exceptional circumstances" for better clarity. Many commenters recommended the standard be clarified to apply specifically to Head Start and include services for five-year-olds in states where compulsory education does not begin until age six.

Response: This standard is not new and we do not believe it has caused significant confusion in the past. However, we made revisions to clarify this requirement is specific to Head Start. Programs may request additional guidance, if needed.

Comment: Some commenters recommended we revise paragraph (b) to establish continuous eligibility for children from the time they enroll in Early Head Start until they enter kindergarten.

Response: As previously noted, eligibility is set by statute. Such a change is outside the scope of this rule.

Comment: We received many comments that supported the provision in paragraph (b)(3) (formerly paragraph (b)(4) in the NPRM) that programs maintain enrollment for children who are homeless or in foster care. Some commenters expressed concern about the proposed standard. Commenters supporting the provision noted its importance to support stability and continuity for children experiencing homelessness and children in foster care. Some commenters stated the standard should be made stronger. Some commenters were concerned about the provision and recommended it be struck because maintaining enrollment would be too costly.

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[42] U.S. Department of Health and Human Services, Administration for Children and Families (2015). *Office of Head Start Program Information Report, 2014–2015.* Washington, DC: Author.

Response: We retained this provision with no revisions. Programs may request technical assistance to support their efforts to maintain enrollment for these children.

Comment: We received comments that supported the provision in paragraph (c) to require a program to use their community assessment to determine if there are families experiencing homelessness or children in foster care in the area who could benefit from services and allowing programs flexibility to reserve up to three percent of slots for special populations. Commenters noted its importance in Head Start serving vulnerable children. Others supported the standard but recommended we expand it in a variety of ways. Others recommended changes, such as making the slot reservation a requirement instead of an allowance, adding additional subgroups for whom slots could be reserved, or allowing up to six percent of slots be reserved. Some commenters requested additional guidance on implementation.

Response: We believe we have achieved an appropriate balance between reserving slots for particularly vulnerable children while maintaining availability for other eligible children who need Head Start services. Reserved enrollment slots will not be counted as under-enrollment. Programs may request additional guidance on implementation as necessary. We made no revisions to this standard.

Comment: Some commenters expressed concern about the flexibility to reserve slots for the specified populations and concerns about the timeline allowed for such reservation, as described in paragraph (c). Some commenters were concerned the slots would remain unused throughout the year and some were concerned that it was unrealistic to fill the slots within 30 days. Others were concerned that the record keeping would be too burdensome.

Response: The rule is clear that if the reserved enrollment slot is not filled within 30 days, the slot becomes vacant and then must be filled within an additional 30 days. We believe we have achieved an appropriate balance between reserving slots for particularly vulnerable children for an appropriate length of time while maintaining availability for other eligible children. We believe this provision will foster enrollment of particularly vulnerable children and do not agree that it is too burdensome. We note that programs are allowed but not required to reserve such slots.

Comment: We received comments in support of and opposed to the standard proposed in paragraph (d) for programs to consider the feasibility to enroll children from diverse economic backgrounds who would be funded from other sources. Commenters were concerned this standard could lead to serving fewer Head Start eligible children. Other commenters requested clarifications.

Response: As noted previously, we revised a related standard in § 1302.11(b)(3) to better clarify that programs must consider the feasibility of operating mixed-income programs but that they must not enroll children from diverse economic backgrounds if it would result in a program serving less than their eligible funded enrollment. We believe this additional clarification addresses commenters' concerns that the proposed standard would mean fewer eligible Head Start children would be served. To further clarify our intent, we revised the standard in paragraph (d) to reduce redundancy and make it clear that children from diverse economic backgrounds who are funded with other sources are not considered part of a program's eligible funded enrollment. We think § 1302.11, which addressed how a program should consider their community assessment, is the more appropriate placement for consideration of the feasibility of mixed-income groups.

Section 1302.16 Attendance

This section included provisions to support attendance. Research finds that attendance is essential for children to benefit from program experiences that promote success in preschool and beyond.[43] [44] [45] Therefore, in addition to provisions from the Act to address systemic issues of a program's low monthly average daily attendance, we included new proposals to emphasize the importance of regular attendance for each child. Commenters generally supported the new emphasis and some commenters noted it would help programs identify family needs. However, many commenters opposed or expressed concern about the specific proposals and offered alternative suggestions. We discuss these comments below.

Comment: We received many comments about the requirement in paragraph (a)(1) that programs contact parents if a child is unexpectedly absent and the parent has not contacted the program within one hour. Many commenters opposed the requirement, and stated it was too prescriptive and cumbersome. Some commenters also found the provision unclear and objected to the one-hour timeline. Some commenters supported the one-hour timeline because it promoted child safety and reduced the risk of a child being left in a car or on a bus.

Response: We believe it is critically important that programs contact parents in a very timely manner to ensure children's well-being. We revised the requirements in paragraphs (a)(1) and (2) to be more systems-focused and have clarified that the program must "attempt to" contact the parent because it may not always be possible to reach the parent. However, we believe it is important for programs to ensure children's well-being by contacting parents when children are unexpectedly absent and parents have not contacted the program within one hour of program start time, so we have maintained this requirement.

Comment: We received many comments on the provision in paragraph (a)(2) about steps a program must take to improve attendance for children who have four or more consecutive unexcused absences or are frequently absent. Some commenters were generally supportive of this provision. Many commenters expressed concerns that the requirements were too prescriptive or too costly for programs. Some commenters were concerned that since low attendance was often linked to family crises, home visits would pose significant challenges. Many commenters stated the emphasis on attendance should be more systems-focused. Commenters recommended alternative language. Some commenters requested additional guidance for implementation.

Response: We believe regular and consistent attendance is essential for programs to support children's early learning. We also think that inconsistent attendance often indicates a program needs to make more efforts to engage with and support families. We think it is very important for programs to realize the importance of regular attendance and work with families when appropriate to foster regular attendance. Therefore, we retained a strong focus on supporting attendance in the final rule. To further strengthen this requirement and clarify when frequent absences must be addressed, we revised paragraph (a)(2)(iii) to reflect that programs must conduct a home visit or other direct contact with parents if children experience multiple unexplained absences, such as two or more consecutive unexplained absences. Unexplained absences would not include days a child is sick if the parent let the program know that the child was out because of an illness. We also added paragraph (a)(2)(iv) to require programs to use individual child attendance data to identify children with patterns of absence that put them at risk of missing ten percent of program days per year and develop appropriate strategies to improve individual attendance among identified children, such as direct contact with parents or intensive case management as necessary. Programs may request technical assistance to address the causes of absenteeism.

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[43] Ehrlich, S.B., Gwynne, J.A., Pareja, A.S., & Allensworth, E.M. (2013). Preschool Attendance in Chicago Public Schools. *Research Summary.* University of Chicago Consortium on Chicago School Research.

[44] Community Action Project Tulsa County. (2012). *Attendance Works Peer Learning Network Webinar.*

[45] Connolly, F., & Olson, L.S. (2012). Early Elementary Performance and Attendance in Baltimore City Schools' Pre-Kindergarten and Kindergarten. *Baltimore Education Research Consortium.*

Comment: Some commenters stated the requirement about program-wide attendance in paragraph (b) should be triggered at a lower percentage for infants and toddlers.

Response: We believe the 85 percent threshold is appropriate for Early Head Start and Head Start programs and has been the long-standing threshold in the previous Head Start regulation. We retained this provision as proposed.

Comment: We received many comments about the provision in paragraph (c)(1), which provides flexibility to support the attendance of children experiencing homelessness. Many commenters were concerned about the reference to birth certificates in our proposal for fear it implied programs can require birth certificates for enrollment. Many commenters supported the flexibility but were concerned about how to satisfy federal and state requirements when they are in conflict. Some commenters were concerned this standard would pose a public health concern.

Response: Birth certificates are not required for enrollment. We have revised paragraph (c) to eliminate confusion. Additionally, in order to address the conflict between the program performance standards and state licensing requirements and any public health concerns, we have clarified that programs must defer to state licensing requirements. However, since it is important that children without proper immunizations get up to date and attend Head Start as soon as possible, we also strengthened the standard to require programs to work with families to get children immunized as soon as possible.

Comment: Some commenters stated the provision in paragraph (c)(2) about providing transportation for children experiencing homelessness where possible was too stringent. Some commenters stated it was not strong enough and recommended requirements that mirror those in the McKinney-Vento Act. Some commenters requested additional clarification about using program funds if community resources are unavailable.

Response: A program may use program funds to provide transportation to all children in the program or to a subset, such as homeless children. However, approximately 40 percent of programs provide transportation services. We believe the requirement for programs to use community resources if available to transport homeless children while allowing but not requiring the use of program funds to do so is the appropriate approach, and have not changed this provision.

Section 1302.17 Suspension and Expulsion

This section outlines the program performance standards pertaining to the suspension and expulsion of Head Start children. These standards codify long-standing practice to prohibit expulsion of Head Start children. However, given recent research that indicates suspensions and expulsions occur at high rates in preschool settings,[46] [47] [48] we explicitly require all programs to prohibit expulsion and limit suspension in Head Start and Early Head Start settings and further require programs to take steps, based on best practices, to support the social, emotional and other development of children who demonstrate serious behavioral issues.

In general, many commenters were supportive of the standards described in this section. However, some commenters expressed concern about the implementation of these standards if, for example, parents refuse mental health consultation, programs lack specialized staff, and alternative placements for children are not available. Below, we summarize and respond to these and other comments on this section.

Comment: Commenters recommended we define "suspension" and "expulsion."

Response: We did not add definitions for these terms. We note that other Federal laws contain requirements and safeguards when children with disabilities are suspended or expelled. IDEA's discipline procedures apply to children with disabilities as defined in section 602(3) of IDEA in Head Start Programs. See IDEA section 615(k), 20 U.S.C. 1415(k) and 34 CFR 300.530 through 300.536.

There are other safeguards for children who are not served under IDEA but who are protected under Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794, and Title II of the Americans with Disabilities Act (Title II), 42 U.S.C. 12131 *et seq.*, because they satisfy the definition of disability in those Acts. Those statutes, IDEA, Section 504, and Title II also do not contain definitions for the terms "suspension" or "expulsion." We expect programs to consider their ordinary and customary meanings. However, we think this section makes clear our expectations about supporting children instead of suspending and expelling them.

Comment: Some commenters suggested we revise the suspension requirements in paragraph (a) to provide more support for children who may be temporarily suspended for challenging behavior. Others recommended we completely prohibit suspension instead of requiring programs to severely limit the use of suspension. Some commenters suggested we require programs document the support services provided to each child during a temporary suspension and upon their return. Commenters also recommended we require programs to conduct home visits during any temporary suspension. Other commenters requested we require specific interventions, such as early childhood mental health consultation before a temporary suspension is permitted.

Response: We agree that instances where temporary suspensions are appropriate should be considered extremely rare. Young children with challenging behaviors should be supported and not excluded. Therefore, the provision in paragraph (a)(1) requires the program to prohibit or severely limit the use of suspension. We agree that our requirements for limitation on suspension did not appropriately focus enough on preventive and support services. We revised paragraphs (a)(3) and (4) to ensure appropriate support services in the extremely rare circumstances where programs consider suspension for the safety of children or staff. We revised paragraph (a)(3) to require programs to engage with mental health consultants and parents before a program decides on a temporary suspension. In addition, we revised paragraph (a)(4) to engage with a mental health consultant and parents and provide supportive services such as home visits, and written plans of action, to support a child during a temporary suspension to facilitate their full participation in all program activities.

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[46] Gilliam, W.S. (2005). Prekindergarteners left behind: Expulsion rates in state prekindergarten systems. New York, NY: Foundation for Child Development.

[47] Gilliam, W.S., & Shahar, G. (2006). Preschool and child care expulsion and suspension: Rates and predictors in one state. *Infants & Young Children, 19,* 228–245.

[48] Lamont, J.H., Devore, C.D., Allison, M., Ancona, R., Barnett, S.E., Gunther, R., & Young, T. (2013). Out-of-school suspension and expulsion. *Pediatrics, 131*(3), e1000–e1007.

Comment: Many commenters generally supported our requirements, described in paragraph (b), to prohibit expulsion. Many commenters appreciated our focus on positive interventions instead of punishment, indicated that they already prohibit expulsion in their programs, or wanted clarification that expulsion would not be permitted under any circumstances. Some commenters suggested that Head Start programs do not suspend or expel children often enough to warrant federal requirements, and questioned why such requirements were necessary.

Some commenters were concerned about an outright prohibition on expulsion in paragraph (b). Commenters were worried it limited their options and raised concerns about how to effectively and safely implement this in their programs. Commenters raised a number of different issues, including parents refusing mental health consultation or disagreeing that their child needs additional services; danger to other children and staff; liabilities to programs; programs not having the specialized staff or access to appropriate services; and potential conflicts with state licensing. Some commenters suggested that expulsion should be allowed as a last resort for programs, that in some instances the threat of expulsion prevents parents from being disruptive to programs, and suggested that keeping children in the program may not be in their best interest. Finally, some commenters requested additional guidance on how to effectively and appropriately implement these requirements, some expressing concern about losing funding if programs are "forced" to suspend a child.

Commenters also offered recommendations they felt made the requirement stronger, including requiring programs to provide staff with access to in-service training to prevent child suspension and expulsion, implementing specific strategies to address challenging behaviors such as trauma assessments, and providing extra funding to hire additional trained staff. Some commenters suggested we add a requirement for parents to consent to mental health consultation to address their concern.

Response: We do not think young children should be expelled from Head Start because of their behavior. Though we do not believe it to be a widespread problem in Head Start, recent research finds that preschool children are being expelled at alarming rates nationwide.[49] Stark racial and gender disparities exist in these practices. Young boys of color are suspended and expelled at much higher rates than other children in early learning programs and African American girls are suspended at much higher rates than other girls.[50] Suspension and expulsion in the preschool early years is related to less educational achievement later and negative long-term outcomes.[51] [52] For these reasons, HHS has recommended this problem receive immediate attention from the early childhood and education fields.[53] It is Head Start's mission to provide high-quality early education to vulnerable children and therefore, it is especially critical that Head Start ensure children with challenging behaviors are supported, rather than expelled.

We understand commenters' concerns but believe we struck the appropriate balance. Children and staff will be best supported by our firm stance against expulsion; our requirements for best practice for prevention and intervention for children's mental health and social and emotional well-being in § 1302.45; requirements in paragraph (a)(2) that permit a program to temporarily suspend a child if there is a serious safety threat that cannot be addressed through the provision of reasonable modifications; and our requirements in paragraph (b)(2) for supportive best practices when a child exhibits persistent and serious challenging behaviors. As a last resort, as described in paragraph (b)(3), a program may transition a child directly to a more appropriate placement if it has explored and documented all possible steps and collaborated with all parties involved in the child's care. Programs should provide children with the accommodations they need based on screenings and evaluations while they are awaiting a more appropriate placement.

We believe it is critical to support parents from the time their children enroll in Head Start and to partner with them to address challenging behaviors. We understand that some parents may be reluctant to engage in mental health consultations. Programs must work to support a program-wide culture that promotes child mental health and social and emotional well-being as described in § 1302.45 and as part of that process, take steps to normalize the mental health consultation process. We revised § 1302.45(a)(3) to require programs obtain parental consent for mental health consultation services when they enroll children in the program. This should facilitate mental health consultation and help remove stigma around behavioral supports.

Finally, we agree it is important for programs to have the tools necessary to address behavioral problems in children without the use of suspension and expulsion. Programs are required under § 1302.92(c)(4) to implement a system of professional development that supports teachers' ability to address challenging behaviors. Finally, Head Start has a long-standing history of preventing suspension and expulsion practices, and as such, programs should be able to budget accordingly.

Comment: Some commenters suggested revisions to the requirements in paragraphs (b)(2) and (3) that detailed specific steps programs must take to support a child when they exhibit persistent and serious challenging behaviors. For example, commenters stated it was unrealistic to require programs consult with a child's physician since programs cannot compel physicians to participate in a consultation process. Some commenters also stated the phrase "exhaustive steps" was too subjective and requested clarification.

Response: We agree and made revisions accordingly. We revised both paragraphs to require consultation with a child's teacher instead of their physician, and revised paragraph (b)(2) to include consideration of the appropriateness of providing needed services and supports under Section 504 of the Rehabilitation Act. We also revised both paragraphs to replace "exhaustive steps" with "explore all possible steps and document all steps taken." We think this reflects best practice, clarifies our intent, and gives programs appropriate flexibility to implement best practices that are most appropriate for a particular child.

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[49] Gilliam, W.S., & Shahar, G. (2006) Preschool and Child Care Expulsion and Suspension: Rates and Predictors in One State. *Infants and Young Children, 19*(3), 228–245.

[50] U.S. Department of Education, Civil Rights Data Collection (2016). Retrieved from: *http://www2.ed.gov/about/offices/list/ocr/docs/2013-14-first-look.pdf,*

[51] Lamont, J.H., Devore, C.D., Allison, M., Ancona, R., Barnett, S.E., Gunther, R., & Young, T. (2013). Out-of-school suspension and expulsion. *Pediatrics, 131*(3), e1000–e1007.

[52] American Psychological Association, Zero Tolerance Task Force Report (2008). An evidentiary review and recommendations.

[53] *https://www.acf.hhs.gov/sites/default/files/ecd/expulsion_suspension_final.pdf.*

Comment: Many commenters stated we needed to revise our expulsion requirements to allow programs to transfer children with behavioral problems to the home-based option. Some commenters stated a classroom setting was not developmentally appropriate for some children.

Response: We believe programs must make significant efforts to support the full integration of all children into every program option. Effective implementation of the requirements to support children's mental health and social and emotional well-being, described in § 1302.45 will support positive learning environments, integrate preventive efforts to address problem behaviors, and engage mental health consultants to support families and staff when challenging behaviors arise. These types of comprehensive services are foundational to Head Start. If a child exhibits problem behaviors in the classroom, the child may be eligible for appropriate special education and related services, to be included in an Individualized Education Program (IEP) developed in accordance with section 614(d) of the IDEA or an Individualized Family Service Plan (IFSP) developed in accordance with section 635 of the IDEA, or it may be appropriate to provide the child needed supports under Section 504 if the child satisfies the definition of disability in section 705(9)(b) of the Rehabilitation Act. We think moving a child to a home-based option without first exploring all the possible steps described in paragraph (b)(2) is a form of expulsion. If a child is exhibiting persistent and serious challenging behaviors in the classroom setting, programs must implement the process described in paragraphs (b)(2) and (3) to facilitate the child's safe participation in the program. Only as a last resort, and after exploring all possible steps and documenting all steps taken, programs may determine if a child needs an alternate placement such as on-going participation in a home-based program model.

Comment: Some commenters recommended we explicitly prohibit suspension or expulsion of children for poor attendance or because they are picked up late from the program.

Response: We agree children should not be suspended or expelled for poor attendance or parental tardiness. In § 1302.16(a)(1) and (2), we already describe steps programs must take if a child is unexpectedly absent, has multiple consecutive unexpected absences, or is frequently absent.

Comment: Many commenters stated our requirement in paragraph (c) that states parent participation is voluntary and not required as a condition of a child's enrollment was too vague.

Response: This requirement was also in the previous Head Start Program Performance Standards. We moved this provision to § 1302.15(f) to improve clarity.

Section 1302.18 Fees

This section describes our policy on fees. We maintain the overarching policy that programs are prohibited from charging parents of eligible children a fee for their child's participation in a Head Start program. We made revisions to improve clarity.

Comment: Some commenters requested clarification of the requirement in paragraph (b)(1). For example, some commenters requested clarity on how long the program day could be, and how long the additional funded hours could be. Additionally, some commenters expressed concern about whether they would be able to assess fees for the pre-k funded portion of the day.

Response: Hours per day, and thereby additional funded hours, depend on the length of the day the program is operating Head Start. Programs may assess fees only for additional hours beyond the Head Start day. The ability to assess fees for hours beyond the Head Start day is subject to state and local requirements. We revised this provision to improve clarity.

Comment: Commenters requested clarity about the impact that paragraph (b)(2) would have on cost allocation. Specifically, some commenters expressed concern that programs should not be able to "double dip" in funding, stating that we would need to ensure additional funds go to additional services. Other commenters asked whether collected fees would supplant current funding. Some commenters requested clarity about whether private pay children would be considered Head Start children or would be counted as part of enrollment.

Response: All grantees receiving Head Start funds are required to comply with the provisions of 45 CFR part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements. Part 75 includes regulations requiring that all costs be allocated among multiple funding sources in accordance with relative benefits received. These regulations assure that programs cannot "double dip" or charge the same expense to more than one funding source. Head Start is designed to increase the number of low-income children receiving high-quality, comprehensive early education services that help facilitate healthy development, including physical and social and emotional development, and prepare them for school success. To meet this goal, it is critical that Head Start funds do not supplant existing services. Existing laws and regulations addressing cost allocation and non-supplantation are not re-stated in the proposed regulation. However, to improve clarity, we revised paragraphs (b)(1) and (2) to better articulate when fees may be charged to enrolled and non-enrolled families.

Comment: Some commenters supported the standard in paragraph (b)(2) to encourage mixed income settings and the ability of Head Start programs to charge a fee to private pay or otherwise funded children. Other commenters expressed concern about these provisions or explicitly opposed the requirement in paragraph (b)(2) that allowed programs to charge fees to children who are not Head Start eligible to encourage mixed-income settings. For example, some commenters were concerned this would put Head Start in competition with other private pay providers in the community or were concerned about unintended consequences for eligible children in terms of access.

Response: Research on peer influences suggests that low-income children achieve better learning outcomes in mixed-income settings.[54] [55] We do not believe that allowing Head Start programs to operate mixed-income classes will have a negative impact on other private pay providers in a community. This requirement does not allow programs to serve fewer eligible children than their Head Start funded enrollment. However, to further clarify our intent mixed-income settings must in no way displace Head Start eligible children, we revised §§ 1302.11(b)(3),

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[54] Mashburn, A.J., Justice, L.M., Downer, J.T., & Pianta, R.C. (2009). Peer effects on children's language achievement during pre-kindergarten. *Child Development, 80(3),* 686–702.

[55] Henry, G.T., & Rickman, D.K. (2007). Do peers influence children's skill development in preschool? *Economics of Education Review, 26(1),* 100–112.

1302.15(d), and paragraph (b)(2) in this section.

Comment: Some commenters asked for clarification or suggested revisions for additional specificity in paragraph (b)(2). For example, commenters requested clarity about the definition of "diverse economic backgrounds" and whether over-income tuition could be applied to non-federal match requirements. Some commenters asked for clarity about whether paragraph (b)(2) allows programs to charge fees to Head Start eligible children during the non-Head Start portion of the day. Additionally, commenters requested clarity about whether Head Start children can be expelled if their parents do not pay the fees for non-Head Start hours. Some commenters suggested that expulsion should be possible, because otherwise it would be impossible to hold parents accountable for paying fees. Other commenters suggested that we ensure Head Start children cannot be turned away if the portion of day funded by child subsidies requires fee and the parents cannot pay.

Response: We believe that it is important for programs to have local flexibility to define what economic diversity means in their own communities so did not include a definition. Any non-federal match must support services to Head Start eligible children during the Head Start day. Programs can charge fees to Head Start eligible children during the non-Head Start portion of the day. However, programs cannot predicate a child's participation in the Head Start portion of the day on enrollment in the non-Head Start portion of the day or payment of any fees.

Comment: Some commenters requested clarification about the proposed regulations covering fees for services under Part C of IDEA in paragraph (b)(3). Commenters noted the provision referenced Part B of IDEA, not Part C.

Response: We agree with commenters that the reference to IDEA in paragraph (b)(3) was incorrect and unnecessary. We removed this requirement.

Comment: Commenters noted that both standard fees and "de facto fees" should be prohibited, including requiring parents to provide diapers, formula, or food and asked whether fees for special events like field trips were included.

Response: We have codified the requirement to provide diapers and formula in Head Start programs in § 1302.42(e)(1) of the standards and clarified here that fees are not allowed for activities, such as field trips, that are part of the Head Start day.

Program Structure; Subpart B

In this subpart, we combined all previous performance standards related to program options into one coherent section and indicated different requirements for Head Start and Early Head Start when necessary. We set standards for how programs should choose a program option; defined the requirements for ratios, group size, and service duration for each of the program options; and outlined the waiver requirements to operate locally designed program options. The majority of the comments submitted on the NPRM provided input on this subpart. In particular, most commenters raised concerns with the proposal to increase the service duration for Head Start children to a full school day and full school year. We discuss the comments and our rationale for any changes other than technical changes to the regulatory text below.

Section 1302.20 Determining Program Structure

This section describes how programs must select a program option and develop a program calendar. The provisions in this section also require that all program options provide comprehensive services, outline the process for conversion of Head Start slots to Early Head Start slots, allow American Indian and Alaska Native programs to reallocate funding, and clarify what are considered Head Start and Early Head Start hours of service.

Comment: Commenters expressed some concerns about the proposed provision in paragraph (a)(1) that programs annually consider whether local needs would be better met through conversion of existing part-day to full-day slots or full-day to full working day slots. Some stated that annual consideration was too often and too burdensome and suggested less frequent alternatives. In addition, the proposals in paragraphs (a)(2) and (3) created some confusion. Some commenters opposed the provision that programs consider conversion to a full year program and others found the language unclear in regards to whether this conversion was mandatory and whether full year meant calendar or academic year. Commenters requested clarification on the proposal in paragraph (a)(3) that requires programs to try to identify alternate funding sources before using program resources to cover extended hours because they found the term "extended hours" confusing and were unsure how meeting this requirement would be evaluated.

Response: We revised paragraphs (a)(1) and (2) and struck paragraph (a)(3) from the NPRM to improve clarity of what is required of programs. The requirement for programs to annually consider whether they should convert to a full year program was not meant to require actual conversion but rather for programs to annually consider whether such a conversion would better meet the needs of their community. Paragraph (a)(2) now makes clear that consideration of conversion and ways to promote continuity of care should take place as part of the annual review of the community assessment described in § 1302.11(b)(2). In addition, we replaced the term "extended hours" in what was paragraph (a)(3) in the NPRM with "full working day services" for improved clarity in paragraph (a)(2) in the final rule. We believe annual reconsideration of whether a program's model is meeting local needs is appropriate.

Comment: We received comments on provisions in paragraphs (a)(1) and (3) of the NPRM regarding conversion to Early Head Start. Some commenters strongly supported these provisions. Some stated that annual consideration was too often and too burdensome and suggested less frequent alternatives. Some commenters requested that additional clarification be added to the regulation, such as noting that conversion was allowable for grantees who did not currently operate Early Head Start and that regional offices should approve or deny conversion requests within a stated timeline. Other commenters suggested the standards should explicitly allow a reduction in funded enrollment for programs that choose to convert Head Start slots to Early Head Start slots.

Response: No changes were made to the provisions regarding conversion of slots to Early Head Start, which we believe are appropriately addressed in paragraph (c), with the exception of a technical correction that the policy council would also need to approve the request and a clarification that programs should update their school readiness goals to reflect the ages of children they serve. There are no statutory or regulatory prohibitions to prevent grantees that do not currently operate Early Head Start from converting slots. We agree that a reduction in funded enrollment is a likely outcome of conversion because of the higher relative costs of serving infants and toddlers, but this does not need to be included in the regulation. We understand there is concern about the time required to process conversion requests but note that the process follows the clear requirements set forth in statute and further clarified in this rule.

Comment: Some commenters asked for clarification about whether a blended or braided funding model would be allowed to achieve the full school day requirement. Some sought additional clarification about which Head Start standards would need to be met during hours of operation not funded by Head Start. Some commenters also sought additional clarification about which hours must meet Head Start standards and noted that they would not be able to meet Head Start standards for before and after care. Similarly, commenters asked for clarification about whether the ratio and group size requirements only referred to program hours funded by Early Head Start or Head Start.

Response: The NPRM intended to convey that hours of service that meet Head Start standards would be counted toward calculation of Head Start service duration, regardless of whether those hours were funded by federal Head Start funding or another source. We understand the need for innovative funding models to leverage funds to more efficiently meet the needs of children and families. To eliminate confusion about whether these funding models are an allowable approach to meet the service duration minimum requirements, we added paragraph (d) to clearly state that programs may consider hours of service that meet the Head Start Program Performance Standards, regardless of the source of funding, as hours of planned class operations. We encourage programs to continue to seek innovative ways to fund their program models while meeting high-quality standards throughout the day. However, we acknowledge that ratio requirements, as well as all Head Start program performance standards, apply only during the hours of planned class operations for Head Start and Early Head Start.

Section 1302.21 Center-Based Option

This section defines the setting for the center-based program option and sets requirements for ratios, group size, service duration, calendar planning, licensing, and square footage. Most comments addressed the service duration proposal for Head Start center-based programs.

Comment: The NPRM proposed to increase the minimum hours and days of program operation for Head Start preschoolers in the center-based option. The majority of comments addressed this proposal. The NPRM also proposed making the double session model only available as a locally designed program option, instead of as a standard program model. Some commenters supported the proposed increase in the hours per day and days per year, regardless of available funding. Some specifically supported the move to full school day (minimum of 6 hours per day) or full school year (minimum of 180 days per year), and still others supported both provisions as the standard option for Head Start. Reasons for their support included: Significant increases in school readiness; the strong research base; alignment with state pre-K and K–12 systems; increases in the employment rates of low-income parents; child needs for more time to reach learning goals; doubling the amount of time Head Start children would be exposed to high-quality instruction and services; and better meeting parent needs. Others recommended we re-calculate the cost per child needed for each grantee to move to the proposed standard dosage for center-based services.

Some commenters supported the proposal to increase program duration for Head Start preschoolers, but only if funding is available to support the changes. These commenters noted the research base and potential improvement for children's outcomes, but stated that they would not support the policy without adequate funding because it would deprive many children of early learning opportunities due to a decrease in available Head Start slots. Some commenters generally agreed we should increase program duration for Head Start preschoolers, but they also raised concerns. We discuss those concerns in more detail below.

Some commenters suggested alternative minimums to the 180 days per year and 6 hours per day proposed in the NPRM. Some suggested that the requirements for the length of day and year be shorter than those proposed in the NPRM, but longer than previous standards. Commenters suggested taking an annual hours approach to program duration, such as 1,020 or 1,080 hours per year for Head Start preschoolers, to allow programs greater flexibility to design what works best for their community. Other commenters suggested requiring a specific percent of slots for each grantee, such as 50 or 75 percent, meet an increased duration requirement and allowing the remaining slots to be more flexible. Other commenters suggested that the minimum duration requirements should vary based on child age. Some suggested that the increase in duration should be encouraged, or optional, but not required. Some commenters asked if programs currently operating at a lower dosage would be "grandfathered in" and allowed to continue operating under the old program performance standards. Others suggested that the required hours per day should be less than what would trigger a nap requirement under local licensing rules. Some commenters recommended allowing programs to offer a "menu" of varied program models based on community assessments with an ability to shift slots between models over the course of the grant to meet changing needs. Some other commenters suggested that the increased duration requirements for Head Start (180 days) should align with the requirements for Early Head Start (230 days). Some commenters asked why duration requirements are not higher than those proposed in the NPRM, given the research on summer learning loss and evidence that children benefit from longer duration, and the need for a longer day to accommodate working families.

Many commenters raised concerns about the impact of these changes on partnerships and collaborations with public schools. Commenters proposed alternative minimums or suggested that programs be allowed to align their calendar with the local school district or state requirements for K–12, to facilitate partnerships with schools. Some noted that their school district or state tracks time in hours per year and suggested that this same flexibility be applied to Head Start. Commenters also raised concerns about the challenges of operating longer than their local schools. Specific concerns included disruptions to transportation, facility space, and food service; the ways service days are calculated; and union agreements. Some commenters stated that double sessions are sometimes the best option when working with school districts due to space limitations and transportation. Others stated that attendance is low when Head Start is in session but the school district is not.

The majority of commenters either opposed or expressed significant concerns with the provisions to increase the program day and year for Head Start preschoolers, with many citing multiple reasons for their concerns or opposition. Some of these commenters were generally against the proposal to increase program duration, without going into specific reasons for their opposition. Many commenters were concerned or opposed due to the loss of Head Start slots that would occur without appropriate funding. In this context, some were specifically concerned with the elimination of double sessions and only being able to serve half the number of children in their community. Some commenters agreed that children would benefit from the increased exposure to Head Start, but they felt that this benefit was not worth other children and families no longer receiving Head Start services. Some suggested that the reduction in the number of slots could cause additional instability in already fragile communities and that there are no other high-quality early childhood education options available in some communities. Some commenters suggested delaying implementation of the new requirements until sufficient funding is in place to prevent enrollment reduction. Others expressed that any additional money should be used to increase access to Head Start, as opposed to program duration.

Some commenters stated that the increased duration was not developmentally appropriate for preschoolers. Some noted that transportation in rural areas would make the day even longer for children. Some suggested that a 6-hour day may not be appropriate for certain groups of children, such as 3-year-olds, children with challenging behaviors or special needs, or DLLs. Some commenters asserted that a longer year is not appropriate for preschoolers. Others specifically stated that moving to a program that operates five days per week (as opposed to 4 days) is not appropriate for children this age.

Many commenters expressed concern or opposition to the proposed operation minimums for preschoolers because they would limit the ability of programs to address the unique needs of the local communities and families they serve and/or because the proposed requirements do not take into account parental choice or preferences. Commenters stated the proposed requirements would prevent creative and innovative program designs that would be more responsive to community needs. Some commenters said that it does not support the cultural values of all families, such as American Indian and Alaska Native or immigrant families.

Some commenters opposed or expressed concerns about the proposed increase in service duration for Head Start because of the logistical challenges programs would face, including significant disruptions to community collaborations. Some commenters stated that collaborations they use for transportation would be severely disrupted. Others noted they would lose access to facilities because their community partnership would not be able to provide full-day space. Many of these commenters raised concerns about the lack of adequate or reasonably priced facilities in their area. Some commenters were concerned with the challenges they would face finding enough high-quality teachers for new classes. Some commenters raised concerns about negative impacts on partnerships with child care providers and family eligibility for child care subsidies to provide families with care for a full working day. Some commenters noted that children who currently receive full day services through the combination of a half-day of Head Start and half-day of state pre-k could be negatively impacted by the duration proposal.

Some commenters opposed or expressed concerns about the proposed increase in duration for Head Start preschoolers because of the potential impact on teachers and other staff. Some commenters were concerned about the loss of staff jobs that would result without adequate funding to support the increased duration, noting this would have a negative impact on the economy and local community. Commenters were concerned about how the move to a longer school day or longer school year would increase the burden on teachers and reduce time for other necessary activities, which would undermine program quality. Some suggested that this would increase teacher stress, burnout, and turnover. These issues were of particular concern to some programs that believed they would have to move from a 4-day per week to a 5-day per week schedule. Commenters were also concerned that the proposed model would make it more difficult to recruit and retain highly qualified staff. Commenters noted the need to pay teachers more in order to offset the workload associated with the increased program duration. Some commenters were concerned about the loss of staff jobs that would result without adequate funding to support the increased duration and stated this would have a negative impact on the economy and local community.

Some commenters stated that the research cited in the NPRM was not adequate or appropriate to justify the longer day and/or year for Head Start preschoolers. Some commenters stated that longer duration is not necessarily an indicator of higher program quality. Some commenters stated that moving to full school day services would not increase instructional time because of time that would need to be devoted to naps, meals, and transitions. Some commenters expressed concern with increasing duration for Head Start preschoolers because their state or municipality still has part-day, part-week, or optional kindergarten, or part-day state-funded preschool. Some commenters expressed concern about state licensing laws that would become applicable with a longer program day. Some commenters raised concerns about the impact on their non-federal share match if they served fewer families.

Response: We made significant changes in paragraph (c) to the requirements for service duration for preschoolers in Head Start center-based settings. We believe, and research indicates, that strong child outcomes are best fostered through high-quality early education programs that provide at least a full school day and full school year of services and that children are best served if Head Start programs continue to move toward this goal. We do not agree that the increased service duration is developmentally inappropriate for preschoolers, including three-year-olds, or that the research we cited is inadequate to justify these proposals. While the research does not identify a specific threshold, there is ample research that points to increased duration in achieving positive child outcomes.[56] [57] [58] [59] [60] [61] [62] [63] [64] [65] [66]

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[56] Lee, V.E., Burkam, D.T., Ready, D.D., Honigman, J., & Meisels, S.J. (2006). Full-Day versus Half-Day Kindergarten: In Which Program Do Children Learn More? *American Journal of Education, 112(2),* 163–208.

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[59] Downey, D.B., von Hippel, P.T. & Broh, B.A. (2004). Are Schools the Great Equalizer? Cognitive Inequality During the Summer Months and the School Year. American Sociological Review, 69(5), 613–635.

[60] Ehrlich, S.B., Gwynne, J.A., Sorice, E. (2014). *Preschool Attendance in Chicago Public Schools: Relationships with Learning Outcomes and Reasons for Absences.* University of Chicago Consortium on Chicago School Research. Research Report.

[61] Peisner-Feinberg, E.S., Schaaf, J.M., LaForett, D.R., Hildebrandt, L.M., & Sideris, J. (2014). *Effects of Georgia's Pre-K Program on children's school readiness skills: Findings from the 2012–2013 evaluation study.* Chapel Hill: The University of North Carolina, FPG Child Development Institute.

[62] Barnett, W.S., Jung, K., Youn, M.J., and Frede, E.C. (2013). *Abbott Preschool Program Longitudinal Effects Study: Fifth Grade Follow-Up.* National Institute for Early Education Research Rutgers—The State University of New Jersey.

[63] Gormley, G.T., Gayer, T., Phillips, D., & Dawson, B. (2005). The effects of universal pre-k on cognitive development. *Developmental Psychology, 4*(6), 872–884.

[64] Weiland, C., & Yoshikawa, H. (2013). Impacts of a prekindergarten program on children's mathematics, language, literacy, executive function, and emotional skills. *Child Development, 84,* 2112–2130.

Continued

Many Head Start programs, as well as State funded preschool programs already operate for a full school day and a full school year.

However, we agree with commenters about the negative effects of implementing this model in such a way that could lead to significant reductions in the number of children and families served by Head Start programs, and recognize the need to allow programs and communities sufficient time to thoughtfully plan and adjust their operations. Therefore, we made significant changes to the service duration minimums in subpart B for Head Start preschoolers in center-based settings that we believe strike the right balance of giving more children access to a program with full school day and full school year services, while allowing greater local flexibility and more time for communities to adapt and potential funding to be appropriated.

Revisions in paragraph (c)(2) specify a timeline, process, and requirements for programs to phase in full school day and full school year services for all preschool children served in center-based settings. In this rule, we require that each program offer full school day and full school year services, defined as 1,020 annual hours, for at least 50 percent of its Head Start center-based funded enrollment by August 1, 2019, and for all of its Head Start center-based funded enrollment by August 1, 2021. Exceptions to these requirements may be granted through a simplified waiver process, described in § 1302.24 and discussed in further detail in that section below. Paragraph (c)(2)(i) specifies that until the new requirement in paragraph (c)(2)(iv) or (v) is effective, programs that operate five days per week must provide at least 160 days per year of planned class operations for a minimum of 3.5 hours per day and programs that operate 4 days per week must provide at least 128 days per year of planned class operations for a minimum of 3.5 hours per day. In paragraph (c)(2)(ii) double session variations are in effect permitted until July 31, 2021, which gives grantees operating double session slots ample time to plan for full implementation of the new duration standards. Until this time, double session programs must operate for the same minimums described above. These service duration minimums in paragraphs (c)(2)(i) and (ii) are consistent with the previous program performance standards.

Paragraphs (c)(2)(iii) and (iv) set forth an incremental timeline and process for grantees to shift their programs to provide at least a full school day and a full school year of services to all preschoolers in center-based settings. We made this service duration requirement less burdensome by changing the requirement to a total of 1,020 hours annually, as opposed to a minimum number of days per year and hours per day as proposed in the NPRM. This annual hours approach will allow more local flexibility and is consistent with how the majority of states set minimum requirements for how local education agencies set their calendars. In Head Start, it will provide programs greater flexibility to design schedules that meet the unique needs of their communities while maintaining high standards for the amount of instructional time children receive. As stated in paragraph (c)(2)(iii), each grantee will have until August 1, 2019 to provide at least 1,020 annual hours of planned class operations over the course of a minimum of 8 months to at least 50 percent of its Head Start center-based funded enrollment. As noted later, "hours of planned class operations" is defined in part 1305 to clarify that only the hours when children are scheduled to attend count towards the 1,020 annual hours requirement. Paragraph (c)(2)(iv) states that by August 1, 2021 programs must provide at least 1,020 annual hours of planned class operations over the course of at least 8 months for all of their Head Start center-based funded enrollment.

Programs may design a variety of different schedules within the minimum requirements that meet the specific needs of their families, communities, and staff. For example, programs may choose to operate for four or five days a week for either an 8-month program year or year-round, depending on the length of the day they select, as long as they meet the 1,020 annual hour minimum. This flexibility will allow programs to address many of the concerns that were raised in the comments, such as alignment of the summer break with the local education agency's calendar, the availability of facilities, the continuation of partnerships, and state licensing requirements. We clarify in § 1302.20(d) that all hours of service that meet the program performance standards may be considered Head Start hours regardless of their source of funding.

We believe the flexibility of the annual hours requirement will also allow programs to design schedules to minimize additional staff burden that would exacerbate challenges with attracting and retaining qualified staff. There are a variety of successful Head Start models across the country where programs currently provide full school day and full school year services. To address anticipated challenges, programs may choose to develop budgets that increase staff salaries to reflect the additional workload and to design innovative schedules that build adequate time for teacher planning and other activities into each week.

Although some commenters were concerned that instructional time would not increase under increased duration minimums due to time required for naps, meals, and transitions, we believe having the chance to nap during the Head Start day can be very beneficial to consolidate learning and improve overall health.[67] [68] [69] If a program feels their children would be best served by a day without a nap at Head Start, we designed a flexible enough requirement for programs to design a schedule that would not necessitate a nap under state licensing requirements.

Some commenters believed parents do not want or need Head Start services for a longer program day and year. If parents in a particular community truly do not want full school day or full school year services and a program can demonstrate its model effectively supports child learning, then the program can apply for a waiver in accordance with the requirements described in § 1302.24.

Paragraph (c)(3) provides the Secretary the discretion to lower the required percentage of funded enrollment slots for which grantees must offer 1,020 annual hours of planned class operations to the percentage the Secretary estimates available appropriations can support. This provision will allow the Secretary the flexibility to balance the important policy goal of providing all preschoolers with a full school day and a full school year of services in Head Start with the

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[65] Walters, C.R. (2015). Inputs in the Production of Early Childhood Human Capital: Evidence from Head Start, *American Economic Journal: Applied Economics, 7*(4), 76–102.

[66] Yoshikawa, H., Weiland, C., Brooks-Gunn, J., Burchinal, M.R., Espinosa, L.M., Gormley, W.T., Ludwig, J., Magnuson, K.A., Phillips, D., & Zaslow, M.J. (2013). *Investing in Our Future: The Evidence Base on Preschool Education*. Policy Brief. Foundation for Child Development.

[67] Bates, J. E., Viken, R. J., Alexander, D. B., Beyers, J., & Stockton, L. (2002). Sleep and adjustment in preschool children: Sleep diary reports by mothers relate to behavior reports by teachers. *Child Development, 73*(1), 62–75.

[68] Lam, J. C., Mahone, E. M., Mason, T. B., & Scharf, S. M. (2011). The effects of napping on cognitive function in preschoolers. *Journal of Developmental and Behavioral Pediatrics, 32*(2), 90.

[69] Kurdziel, L., Duclos, K., & Spencer, R. M. (2013). Sleep spindles in midday naps enhance learning in preschool children. *Proceedings of the National Academy of Sciences, 110*(43), 17267–17272.

disruption and potential slot loss such a policy might create in the absence of sufficient funding.

In response to concerns about service duration requirements disrupting partnerships with local education agencies, and to reduce burden on programs that would need to seek waivers in these types of situations, paragraph (c)(2)(v) clarifies that a program providing fewer than 1,020 annual hours of planned class operations or fewer than 8 months of service will be considered to meet the service duration requirements if their program schedule aligns with the annual hours provided by their local education agency's requirements for first grade and such alignment is necessary to support partnerships for service delivery.

Additionally, commenters were concerned about the availability of adequate facilities to serve children for a full school day and a full school year. Congress appropriated $294 million in fiscal year (FY) 2016 for grantees to increase service duration. Our cost estimates included in the Regulatory Impact Analysis are for annual operating costs, and we anticipate that a portion of the first annual awards will be available for the purchase or renovation of facilities before programs begin serving children at the higher duration. We also encourage programs to consider partnerships with school districts and child care centers to use existing facilities, which have proven to be successful models for many current Head Start and Early Head Start-Child Care Partnership grantees.

Comment: In addition to proposing to increase service duration for preschoolers, the NPRM proposed to codify long-standing interpretation for Early Head Start in the Act, which describes it as a "continuous" program. We have long interpreted this to mean a minimum of a full school day and full-year of services for infants and toddlers, and defined this in the NPRM as a minimum of 230 days of service per year for a minimum of 6 hours per day. Some commenters wrote in support of the proposal. Others expressed concerns or opposed the proposal for multiple reasons, including concern about a long day for infants, parents would not want services for this long, and program quality would decrease because teachers would have less preparation and professional development time. Some commenters suggested slightly lower minimums, using annual hours or weeks instead of number of days, and/or recommended changing the requirement to allow time for activities like professional development, parent-teacher conferences, and holidays.

Response: We believe it is important to retain the continuous service model for Early Head Start that has existed since the program's inception. However, to provide greater local flexibility and alignment with the policy decision made for Head Start preschoolers, we changed the NPRM requirement from a minimum number of hours per day and days per year to a total number of annual hours of planned class operations. This requirement of 1,380 annual hours can be found in paragraph (c)(1) and must be met by August 1, 2018. Based on our latest data,[70] approximately three-quarters of children attending Early Head Start center-based programs already receive services for 1,380 hours. In paragraph (c)(1)(ii), we also consider Early Head Start center-based programs that are designed to meet the needs of young parents enrolled in public school settings to meet the annual hours requirement if their program schedule aligns with the schedule of their local education agency (LEA), and they provide regular home-based services over the summer break. This specifically supports the innovative models local programs develop to support teen parents and their children.

Comment: Commenters requested clarification on the definition of days (or hours) of planned class operation and whether it would include activities such as professional development, transportation time, and other types of activities or emergencies. Some commenters recommended that the required duration be inclusive of these types of activities. Some commenters were also confused about the definition of "full year" services, interpreting the requirement as a full calendar year without a summer break. Others were unclear about whether programs would still be allowed to operate 4 days per week under the increased minimums.

Response: As noted above, we added a definition to part 1305 for "hours of planned class operations" to clarify that these are hours when children are scheduled to attend and to specify what activities are and are not included in this calculation. Activities such as professional development, teacher planning, parent-teacher conferences, classroom sanitation, and transportation do not count toward the hours of planned class operations. Programs can choose to structure their calendar year to include a summer, holiday, and other breaks to be responsive to their community's cultural traditions and family needs while still meeting the minimum service duration requirements described in paragraph (c). Similarly, programs can choose to operate 4 days per week as long as they meet the service duration minimums. We made additional minor changes to the calendar planning provisions in paragraph (c)(5) to further simplify and clarify the process.

Comment: Commenters wrote in response to the proposed teacher:child ratios and group size for the center-based option described in this section. Some commended the proposal for maintaining strong ratios and group size because it demonstrated commitment to quality and allowed individualization and good classroom management. Others expressed concern that the ratios were too high for all ages and should be lowered. Others recommended greater flexibility. Some commenters requested more flexibility to set ratios for infants that would still meet high standards but align with their state licensing requirements. Some commenters asked for clarification or flexibility on ratios during naptime and other program hours. For example, some were specifically concerned about or seeking flexibility to allow ratios to be met by persons other than teachers. Some commenters were confused about whether class size and group size had the same meaning. We received comments both in support of and against our proposal for how programs should determine the age of the majority of children in a class to set ratios and group size.

Response: We believe this provision allows for the right balance of flexibility while also recognizing the importance of continuity of care. However, in paragraph (b)(2), we added new regulatory language to allow a group size of nine without needing a waiver for infant and toddler classes when the teacher to child ratio is 1:3 or lower. In paragraph (b)(1)(i), we clarify that brief absences of a teaching staff member that cause the group to be out of ratio for less than five minutes are acceptable. In paragraph (b)(1)(ii), we clarify that during naptime, one teaching staff member may be replaced by an adult who does not meet the teaching qualifications required. Thus, while the adult to child ratio requirement remains unchanged during naptime, additional flexibility is granted in how a program must meet that ratio. We believe this provides reasonable flexibility while maintaining high standards. Teachers that are present or staff that are substituted during nap times must have completed the safety training required for their role as staff in § 1302.47(b)(4)(i), including safe sleep practices. Ratios and group size requirements for double sessions are also now included in paragraph (b), as double sessions are now permitted as a standard option until the year 2021, and after but only as a locally designed option. These requirements are consistent with the previous regulation for double sessions. We did not make any changes to the provision in paragraph (b)(1) regarding determination of the primary age of the class. Throughout subpart B, we substituted the word "group" or "class" for "classroom" and replaced "class size" with the more commonly used "group size" to eliminate confusion. Because of this change, and to make clear that the importance of the learning environment as described in § 1302.31 applies to all groups regardless of the characteristics of the physical space, we have added a new paragraph (d)(3) to clarify appropriate ways to make divisions among groups when they are not in physically separate classrooms.

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[70] Submitted by grantees through the FY 2015 Grant Application Budget Instrument.

Comment: Commenters also wrote about our proposal in paragraph (b)(2) to support continuity of care through consideration of mixed age groups for children under 36 months of age. Some found the mixed age groups concept to suggest developmentally inappropriate practice. Others wrote in support of continuity of care practices because of the benefits to children and their parents. Some offered slight changes to the regulatory language and others recommended we provide guidance on implementation of best practices for continuity of care.

Response: We recognize there was some confusion about what mixed age groups might mean in practice. However, we believe best practices for continuity of care will be best delivered through technical assistance and guidance and not through the regulatory process. The provisions in this section facilitate but do not require continuity of care practices.

Comment: Commenters wrote in regard to the center-based licensing and square footage requirements in paragraph (d). Some commenters expressed concern about licensing requirements in relation to schools, seeking greater clarification and noting that some states do not require public schools to be licensed. Commenters also requested clarity on whether programs have to meet licensing standards, or be licensed. Some comments supported and some opposed the center-based square footage requirements, while some stated they were too strict, others suggested they were not strong enough, and others commended the proposal to exclude square footage requirements from the waiver.

Response: We modified the provision in paragraph (d) to make it clear that programs must meet local or state licensing requirements regardless of whether the licensing entity requires that they be licensed. However, we are not requiring that all center-based programs actually be licensed because some states or local jurisdictions may not be able to license entities, such as schools, that are not required to be licensed by state or local law. We believe this provision ensures quality and child safety while allowing for the appropriate amount of local flexibility and variance in types of grantees. As proposed in the NPRM, licensing and square footage requirements will not be eligible for waivers.

Section 1302.22 Home-Based Option

This section defines the setting for the home-based program option for Head Start and Early Head Start and sets requirements for home visitor caseload, service duration, and licensing. We received many comments about our proposal to limit home-based models as a standard option to Early Head Start only. We discuss these and other comments below.

Comment: Some commenters were in favor of removing home-based as a standard option for preschoolers. Commenters stated that home-based models do not meet the educational needs of preschool-age children. Commenters also expressed that, given the significant federal investment in home visiting through the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program, limited available Head Start funding should be targeted towards providing access to center-based programs rather than home-based programs for preschool-age children.

Alternatively, many commenters opposed the removal of the home-based option as a standard option for Head Start preschoolers, citing a number of different reasons. Commenters stated that home-based was the most appropriate delivery model in particular communities, such as rural areas, communities where home schooling is prevalent, and areas with large immigrant or non-English speaking populations. Some commenters suggested that the home-based option is a more appropriate setting for young children, children with severe special needs, disabilities, health problems, or behavior issues, and parents who request home-based to meet children's individual needs. Some commenters stated that center-based programs may not be what parents want for their child. Further, these commenters suggested that many parents are not familiar with resources in the community, do not speak English, or have other barriers that prevent them from taking their children to center-based care. Some commenters cited research or included data demonstrating that home visiting improves outcomes for preschool children.

Response: We agree that a home-based preschool option for Head Start may be appropriate for certain communities, which is why we proposed programs could apply to operate the model through the waiver process. However, to reduce burden on grantees, we reinstated home-based as a standard option for preschoolers in paragraph (c)(2) of this section. Though research indicates that high quality, full-day and full-year center-based settings produce strong outcomes for preschoolers, we recognize that there may be a small number of situations where the home-based model best meets the needs of the child and family. For example, as commenters suggested, in communities with a high home schooling rate, parents would likely prefer home-based services. We do not believe, however, that this model should be used as a means of excluding children from center-based settings. We also do not believe this model should be the only one available to preschoolers and therefore require that it may not be the only option available for Head Start unless the program seeks and receives a locally designed option within the parameters established in § 1302.24. We believe the greater clarity in the community needs provisions in subpart A and the system of program management and quality improvement in subpart J will help programs ensure that the program options they offer truly meet the early learning needs of children and the local needs of the community. Clear minimum requirements for the number of home visits and group socializations for preschoolers in the home-based option have been added in paragraph (c)(2), along with expectations for meeting those minimums in paragraph (c)(3) and for maximum caseloads per home visitor in paragraph (b). These requirements are consistent with the previous standards.

Comment: Commenters also addressed the proposal to increase the service duration for the Early Head Start home-based model to 46 home visits and 22 group socializations per year. Some supported the proposal to increase the number of home visits or suggested a higher number. Other commenters expressed concerns about or opposition to the proposed minimums. Some cited the need for home visitors to have time for paperwork, professional development, and other duties. Some noted difficulty getting families to complete 46 home visits and described family cancellation of scheduled home visits as a key inhibitor. Some of these commenters requested flexibility to allow for visits cancelled by the family. Further, some commenters suggested that the group socialization minimum was too high. Others suggested that 22 was an acceptable minimum number of socializations but requested flexibility for the number of socializations per month. Some commenters objected to the language that programs not replace home visits with medical or social services visits with the home visitor.

Response: Early Head Start was established by Congress as a continuous program. As with the Early Head Start center-based model, the NPRM proposal codified long-standing interpretation of a "continuous program" for Early Head Start in the home-based model by requiring 46 home visits per year. We retained this requirement in paragraph (c)(1)(i). We believe this level of service delivery is central to a successful home-based model and therefore no changes are being made to allow home visits or group socializations to be replaced by medical or social service appointments for the purposes of meeting service duration minimums. However, this does not limit the flexibility of programs to use scheduled home visit time to identify needs and schedule necessary medical or social service appointments. Home visitors should have the flexibility to determine how to best meet their families' immediate needs and still reach the minimum visits focused on child development and education. However, we believe greater flexibility for meeting the number of group socializations is appropriate and changed the requirement in paragraph (c)(1)(ii) to clarify that the number of required group socializations are for each family, not each child. In addition, instead of prescribing two group socializations per month, the standards require the group socializations to be distributed over the course of the program year. Although we expect programs to space group socializations relatively evenly throughout the year, we believe this change will maintain high-quality while allowing local flexibility to address shifting and unexpected needs and schedules of the families programs serve. To address the confusion about requirements to make up cancelled visits, paragraph (c)(3) clarifies that a program must make up planned home visits or scheduled group socializations if canceled by the program in order to meet minimum service duration requirements, and that they should attempt to make up planned home visits when cancelled by the family.

Comment: Many commenters questioned the need to require licensing for group socialization sites. Commenters believed this requirement would put an unreasonable burden on programs by limiting the locations for socializations. Many also stated that group socialization sites should only need to be licensed if they occur in Head Start facilities. Further, some commenters wanted clarification on the conflict between paragraph (a) and (d), noting that community facilities (including libraries and churches), homes, and field trip locations likely would not be licensed.

Response: The language to require licensing for group socialization sites existed in the previous regulation, but we agree this is potentially confusing, unnecessarily limiting, and that not all group socialization sites need to be licensed. However, we do believe it is important that all sites are safe for children and their families. Therefore, to clarify our intent, we removed the proposed licensing requirement for group socialization sites and replaced it with a requirement in paragraph (d) that the areas for learning, playing, sleeping, toileting, preparing food, and eating in facilities used for group socializations meet relevant safety standards.

Comment: Some commenters wrote in reference to the proposal in paragraph (b) that "programs must maintain appropriate ratios during all hours of program operation" and noted this language was unnecessary for the home-based option.

Response: We agree that including ratio requirements for the home-based option was an error and removed that requirement.

Section 1302.23 Family Child Care Option

This section defines the family child care setting and the relationship between the program and the family child care provider, and sets requirements for ratios, group size, service duration, licensing, and the involvement of a child development specialist. Within this section, commenters asked for clarity regarding the relationship with the family child care providers and the program or the requirements for ratios and group size.

Comment: As described in the preamble for § 1302.21, we received many comments on the service duration requirements for center-based and family child care programs, some in favor and some opposed. The comments typically addressed the service duration proposal generally without explicitly referring to the family child care option.

Response: Because the previous program performance standards required that family child care programs operate for hours that meet the needs of families, nearly all family child care providers already meet the increased duration requirements of 1,020 annual hours for Head Start and 1,380 annual hours for Early Head Start. In fact, most family child care programs provide many more hours than these minimums to meet family needs. Therefore, we removed the service duration requirements in § 1302.23(c) proposed in the NPRM, and instead require that family child care programs must operate for sufficient hours to meet the child care needs of families and cannot operate for less than 1,380 hours per year in paragraph (c).

Comment: Some commenters had concerns or questions about requirements specifically related to programs that operate in a family child care setting. Some commenters supported the family child care employment requirements in paragraph (a)(1) because it is important to ensure transparency and a successful partnership. Some commenters suggested the need for greater clarity regarding the ability for programs to either employ or contract with family child care providers. Others opposed the requirement that the program be the employer of the family child care provider, stating that it was overly restrictive and could hinder innovative employment strategies. Some sought additional guidance and other commenters were unclear about, opposed to, or had concerns about the proposed "legally binding agreement" between the program and family child care providers, and recommended we define this phrase.

Some commenters requested general clarity on the family child care option section, including requirements for ratios and group sizes, as well as expectations for identifying alternate sources of funding for extended hours and expectations under paragraph (a)(2) regarding accessibility and the definition of "as appropriate." A commenter recommended that grantees be required to annually share a list of their family child care contracts with the State Collaboration Office for better collaboration with the subsidy program.

Response: We adjusted the language in paragraph (a)(1) to clarify that a program must either have a legally binding agreement with family child care providers or be the employer of the provider(s). We also considered terminology that could be used in place of "legally binding agreement," such as "legally enforceable agreement or contract," but determined that the original phrase accurately represents the necessary legal relationship and is inclusive of contracts. We also adjusted the language in paragraph (a)(2) to clarify that programs using the family child care option need to be able to accommodate children and families with disabilities. Additionally, we revised paragraph (b) to improve clarity of the ratio and group size requirements for the family child care option. We will not require grantees to share a list of family child care contracts with the State Collaboration Office as we do not believe that this is necessary for successful collaboration with subsidy programs.

Comment: Some commenters asked for clarification about the standard in paragraph (b)(4) that requires family child care programs to maintain appropriate ratios during all hours of operation.

Response: In paragraph (b)(4), we restored standards from the previous rule to clarify how family child care programs maintain appropriate ratios. Specifically, we revised paragraph (b)(4) to require programs to make substitute staff and assistant providers available and required a family child care program to ensure providers have systems to ensure the safety of any child not within view for any period.

Section 1302.24 Locally-Designed Program Option Variations

This section describes the requirements for programs to request a waiver to operate a locally designed program option. The comments we received on this section mainly addressed the timeline and process for approval of waivers.

Comment: Commenters expressed a range of opinions on the proposed locally-designed option waiver process. Some commenters were in favor of requiring a waiver based on evidence of community needs and child progress, and noted these requirements would promote accountability, objectivity, and continuous improvement for grantees in evaluating their program design, but still allow for innovation. Others were concerned about the process being burdensome and time-consuming and recommended alternative periods and processes for approval. Commenters were concerned that the criteria that would be used to approve or deny waivers for locally-designed program options would be inconsistent or unfair and requested clarification about what evidence of outcomes would be sufficient to justify approval of a waiver. Commenters expressed concern about waivers being approved in a timely manner.

Commenters also recommended changes to limit the use of waivers. Some commenters recommended locally-designed options should be standard program options and should not require a waiver. Others recommended retaining all program options from the previous regulation as standard options instead of requiring a waiver, or other structures such as having a number of standard duration options that would include part-day/part-year services.

Some commenters expressed support for requiring approval for a locally-designed option every two years, particularly for programs that would seek to waive the requirements for increased service duration, but others opposed this requirement because it would be too burdensome for programs and suggested longer approval periods. Many of these commenters recommended a five-year period of approval that would align with the community assessment and the five-year grant cycle and would strike a better balance between accountability and burden. Some commenters recommended that programs be allowed to shift their program options annually or within their five-year grant if local needs warrant a change without requiring a new waiver.

Response: We made a number of changes to the locally-designed program option waiver described in this section. As described in paragraph (b), we have changed the period of approval for locally designed option waivers to the full project period of the grant to align with the new five-year grant cycles. In addition, due to other changes made in subpart B, we believe many fewer programs will seek waivers, which will improve the timeliness of the process to review and make determinations. In order to ensure programs thoughtfully determine the appropriate program design that supports their long-term goals, we revised paragraph (a) to link the waiver request to achieving program goals in subpart J.

We revised paragraph (c) to clarify exactly which requirements may be waived. Paragraph (c) more clearly states that the responsible HHS official may waive one or more of the requirements contained in § 1302.21(b), (c)(1)(i), (c)(2)(iii), and (c)(2)(iv); § 1302.22(b) and (c); and § 1302.23(b) and (c). These requirements include ratios and group size in center-based settings for children 24 months and older, Early Head Start service duration, Head Start service duration requirements for the percentage of each grantee's slots operating at 1,020 hours, caseload and service duration requirements for the home-based option, and ratios, group size, and service duration for the family child care option. However, if a waiver of group size for children over 24 months is permitted, paragraph (c)(2) specifies upper limits that are allowable under a waiver, which are included to ensure program quality and child safety. Additionally, paragraph (c)(1) clarifies that waivers are not allowable for ratios or group size for children under 24 months, which is discussed in more detail below. Provisions in the NPRM specific to double session requirements under a locally-designed option were struck because double sessions have been retained as a standard option until August 2021. We added additional language in paragraph (c)(3) to clarify the minimum center-based service duration requirements Head Start programs must meet when seeking a waiver from the 1,020 annual hours provisions in § 1302.21(c)(2)(iii) and (iv).

We revised paragraph (c)(4) and added paragraph (c)(5) to clarify what programs must demonstrate in order to receive a waiver. Specifically, in paragraph (c)(4) we require programs seeking any waiver under this section to provide evidence that their locally-designed variation effectively supports appropriate development and progress in children's early learning outcomes. In addition, in paragraph (c)(5), we require programs seeking waivers of service duration to also provide supporting evidence that their variation better meets the needs of parents than the options described in §§ 1302.21 through 1302.23 and to evaluate the effectiveness of the variation in supporting appropriate development and progress in children's early learning outcomes. We believe local flexibility is important but that tax dollars should be spent on program models that are effective in helping close the achievement gap.

Comment: Commenters stated American Indian and Alaska Native programs should not be required to apply for locally-designed option waivers for some of the provisions in subpart B, and specifically requested a tribal exemption from some of the requirements, including extending the length of the day and length of the year.

Response: We provided greater flexibility in subpart B for programs to design their program schedules in a way that best meets their community needs, including the ability to determine the length of summer breaks and the length of the day, while still ensuring American Indian and Alaska Native children reap the full benefits of greater exposure to high-quality early learning. We think this will allow most programs to accommodate important cultural practices and subsistence activities. However, when this additional flexibility is not adequate to meet community needs, we believe it is appropriate that tribal programs, like all programs, would be able to apply for a locally-designed option.

Comment: Some commenters addressed the standard in paragraph (c)(1) to allow programs to seek waivers from ratio requirements for classes serving children who are at least two years old. Some opposed the proposal to allow programs to apply for a waiver for teacher:child ratios for two-year-olds because such waivers would decrease program quality and lessen children's individualized care. Others supported this waiver because it would allow programs the flexibility to better address extreme unmet need in their communities. Some commenters recommended that we set upper limits for ratios approved by waivers so that flexibility could be sought without compromising quality.

Response: We agree with the need for clear limits to group size and teacher:child ratios in locally-designed options so that high-quality is maintained. Therefore, waiver requirements are clarified in paragraph (c)(2)(i) to specify that even with a waiver, a class serving children 24 to 36 months of age may have no more than ten children. Furthermore, in paragraph (c)(2)(ii), we clarify even with a waiver, a class that serves predominantly three-year-old children must have no more than twenty children and in paragraph (c)(2)(iii), a class that serves predominantly four-year-old children must have no more than twenty-four children. As proposed in the NPRM, ratios and group size may not be waived for children younger than 24 months of age.

Comment: Some commenters opposed the proposal to remove the combination option as a standard option. Some commenters felt combination options met their community and parent needs better than the proposed center-based or family child care options, which were the only program options for preschoolers included in the NPRM. Some stated they were against the removal of the combination option because it is an essential part of their service delivery for rural, isolated communities with no other services and not enough children for a center-based program.

Response: We acknowledge there may be some instances in which a combination option can effectively serve a community but think these services are best achieved through the locally-designed option variation described in this section. This locally designed waiver process will ensure these more unique program models are specifically designed to respond to community needs while effectively meeting children's developmental and learning needs and that tax dollars are being effectively spent. As noted below, in changing the waiver approval process from two years to five years, we believe we struck the appropriate balance between accountability and flexibility.

Effective Dates of Subpart B Program Structure Provisions

In the NPRM, we specifically requested comment on the effective dates of the service duration requirements throughout subpart B. We received many comments on what the effective dates should be and discuss those comments and our responses below. The effective date of this rule and dates for specific requirements that will go into effective after the remainder of the regulation are included in the compliance table in the Dates section.

Comment: Commenters raised concerns with the timeline for phasing in the increased service duration requirements. Many of these commenters stated that one year after the rule is final is too fast for careful planning and implementation. Some commenters suggested that grantees be allowed to phase the requirements in as part of their five-year grant cycle, to allow for thoughtful planning among many stakeholders, time to consider funding options, and time to find adequate facilities and qualified teachers. Some commenters suggested that the effective date of the duration provisions should be tied to Congressional appropriation of funds.

Response: We acknowledge the importance of giving grantees sufficient time for thoughtful planning, consideration of community needs, and management of logistics when increasing the duration of their center-based services. Accordingly, we adjusted the effective dates of the increased service duration provisions to better facilitate thoughtful implementation. However, we are also mindful of moving forward to ensure more children receive the higher levels of service duration that we think are important to achieve strong child outcomes.

The requirements for Early Head Start center-based and home-based service duration in §§ 1302.21(c)(1) and 1302.22(c)(1) are effective August 1, 2018 and August 1, 2017, respectively. The majority of Early Head Start programs already operate in accordance with the service duration requirements we establish in this final rule. Therefore, only a small share of Early Head Start programs must increase their service duration to meet the new requirements. Additionally, funding in FY 2016 is available to support all Early Head Start center-based programs that need to increase their service duration and there should be time and resources for them to meet these minimums by 2018.

The requirement for 50 percent of each grantee's Head Start center-based slots to operate for a full school day and full school year in § 1302.21(c)(2)(iii) is effective on August 1, 2019, which is approximately three years following the publication of this final rule. This interim requirement will mean many more families will have access to the educational services for a full school day and full school year within three years. This requirement will increase from 50 percent to 100 percent effective August 1, 2021, as described in § 1302.21(c)(2)(iv). This effective date is approximately five years following the publication of this final rule. The gradual phase-in allows ample time for grantees to plan implementation and align changes with their five-year grant cycle if they choose. The service duration provisions for the Head Start home-based option described in § 1302.22(c)(2), which are unchanged from the previous performance standards, do not require a delayed phase-in.

We also revised the service duration requirement for the family child care option described in § 1302.23(c) to reflect language from previous standards to state that programs must meet the child care needs of families. Although the provision is not explicit that family child care programs must operate for a minimum of 1,380 annual hours, most family child care programs provide many more hours than this to meet family needs and therefore this provision does not require a delayed phase-in.

We clarify in § 1302.24(d) that programs currently approved to operate program models that do not meet the requirements described in subpart B of this rule, such as combination options, may continue to operate in their existing approved program option until July 31, 2018. However, programs must have either an approved waiver to operate a locally designed program option that meets the requirements in § 1302.24 or adopt one or more of the standard program options described in §§ 1302.21 through 1302.23 no later than August 1, 2018.

While we believe the respective August 1, 2018 and August 1, 2019 effective dates of the center-based service duration provisions described in §§ 1302.21(c)(1) and (c)(2)(iii) should give the vast majority of programs enough time to make changes to their service delivery, there may be unforeseen circumstances that arise which may necessitate additional time to complete the transition without disrupting services to children. Therefore, under § 1302.21(c)(4), programs may request a one-year extension of the increased service duration requirements for center-based Head Start and Early Head Start described in § 1302.21(c)(1) and (c)(2)(iii) if necessary to prevent displacement of children enrolled in the program at the time this rule becomes effective.

Education and Child Development Program Services; Subpart C

In this subpart, we combined all previous program standards related to education and child development services. We significantly updated and restructured these requirements to reflect the Act, current research, and best practices in teaching and learning, to strengthen curriculum requirements, and to integrate the *Head Start Early Learning Outcomes Framework: Ages Birth to Five.* We also corrected an imbalance between Early Head Start and Head Start education standards with a unifying birth to five approach.

We received comments on all sections of this subpart. Overall, commenters were supportive and positive about the provisions in subpart C. Commenters noted the subpart provided a much clearer picture of what high-quality early education looks like, reflected research on how children learn, and appreciated our strong focus on practices that promote intentional and effective teaching. Commenters also expressed their support for our focus on intentional teaching practices but recognizing and requiring play and exploration as important to developing school readiness. Commenters supported the curriculum requirements, including the integration of professional development into curriculum implementation. They also agreed with our provisions to use assessments to individualize services. Commenters supported the integration of the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* through subpart C and appreciated our birth to five approach.

We made some changes in response to public comments that further strengthen this subpart. For example, we modified some language and structure to ensure the subpart consistently and appropriately addressed children from birth to age five. In addition, we made changes to further strengthen and clarify effective services for DLLs. There were some recommendations we thought were too prescriptive, did not reflect best practice or research, were outside the scope of this regulation, sought guidance more appropriate for technical assistance, or were not consistent with current research-based practices. Therefore, we did not make changes based on these comments. We address additional comments below.

General Comments

Comment: Some commenters recommended adding language throughout this subpart to recognize family child care providers separately from teachers.

Response: While we recognize the unique role of family child care providers, we believe that it is important that family child care providers be recognized as the teachers of the children they serve, and therefore use the term teachers in §§ 1302.30 through 1302.34 to be inclusive of family child care providers.

Comment: Some commenters expressed concern there were instances throughout this subpart that did not use language appropriate for infants and toddlers.

Response: This subpart addresses Head Start children of all ages. We only included separate standards when developmental differences made it appropriate to do so. We made revisions throughout the subpart, including for example, requirements for responsive care, a broader reference to children's learning experiences as well as activities, and changes discussed in detail below above developmental scope and sequence in curricula. These changes ensure all sections are appropriate for children from birth to age 5.

Comment: Some commenters suggested we specifically include the principles of universal design (UD) and universal design for learning (UDL) in requirements for curriculum objectives, learning materials and spaces, teaching practices, and assessments.

Response: Though we did not revise the regulation to specifically reference UDL, many of its principles are long standing Head Start and Early Head Start requirements that are expanded and enhanced in this final rule. We also did not incorporate the suggestion to require that programs adhere to UD. We agree that UD principles are beneficial for all users of a facility but think we can effectively promote the principles of UD through technical assistance provided for renovation and construction projects.

Comment: Some commenters suggested that we needed to address teacher compensation in order for this subpart to be effectively implemented.

Response: We agree that teacher compensation is vitally important to attracting and retaining effective teachers. However, addressing compensation is outside the scope of this regulation because teacher compensation is determined by Congressional appropriations and local decisions.

Comment: Some commenters stated that the regulation failed to recognize that supporting the home language of DLLs is important in and of itself, separate from the goal of supporting English acquisition.

Response: We believe there is clear language in § 1302.31(b)(2) that emphasizes the importance of supporting the home language of DLLs, separate from the goal of English acquisition. The Act requires that Head Start programs support the acquisition of English for children who are DLLs.

Section 1302.30 Purpose

This section provides an overarching statement of the general purpose and goals for education services in center-based, family child care, and home-based settings for Early Head Start and Head Start programs. We received some suggestions for this section.

Comment: Some commenters recommended the section include a statement that the goal of Head Start is to close the achievement gap.

Response: The purpose of Head Start is stated in the Act and is the foundation for this section, so we made no changes.

Section 1302.31 Teaching and the Learning Environment.

This section includes the key research-based elements of teaching practices and the learning environment and is central to preparing children to succeed in school. It provides programs with the elements for delivering a more intentional and focused education and learning experience that will better promote skill growth and stronger child outcomes without micromanaging local decision-making and creating undue burden.

Commenters were very supportive and expressed that the section appropriately reflected best practice and effectively elevated the research-based teaching practices that support children's learning and development.[71] [72] [73] [74] [75] Commenters supported the alignment with the Framework as well as the explicit recognition of nurturing and responsive interactions as components of effective teaching practices. Commenters noted the benefits of integrating each child's assessment information into teaching practices and supported the focus on development of skills children need to enter kindergarten ready to succeed. Commenters also appreciated the inclusion of play and exploration as key aspects of effective education programming. Others praised our approach to include meals and daily routines in the education section because it denoted their importance as opportunities for learning experiences and activities. We made some changes in response to comments, including minor structural changes to clarify our intent. Additional comments are addressed below.

Comment: Some commenters thought this section should include additional integration of professional development.

Response: We agree that integration of professional development to support effective teaching practices is a key component of a high-quality early education program. Therefore, we specifically addressed this in paragraph (a) to ensure the system of individualized and ongoing professional development supports teachers and in curriculum requirements in § 1302.32. While professional development revisions to this section were limited to those changes, we also increased the standards for the quality of professional development in subpart I.

Comment: Some commenters suggested that paragraph (b)(2) include a focus on "biliteracy" in addition to bilingualism. Commenters noted that the term biliteracy expands on the goals of bilingualism to include a focus on reading, and eventually writing, in the home language.

Response: We agree with this suggestion and we incorporated "biliteracy" into paragraph (b)(2) as well as in the home-based option in § 1302.35(c)(4).

Comment: Commenters asked for clarification and raised concerns about paragraphs (b)(2)(i) and (ii) related to finding bilingual staff or interpreters to work with DLLs, such as lack of bilingual staff with appropriate credentials, especially in rural areas; lack of interpreters due to the rarity of some languages; and a high diversity of languages in the same class. Some commenters suggested this may be particularly challenging with refugee populations.

Response: Based on the best research available, we believe it is critically important to support the development of both English and the home language for children who are DLLs.[76] [77] [78] [79] [80] Additionally, we believe that all teachers, including those who only speak English, can support the development of DLLs. However, we also understand that in certain instances, such as when there are multiple non-English languages in the same class, it may be difficult to have program staff or interpreters present that speak all languages. In these instances, we encourage programs to collaborate with outside entities to ensure the presence of multiple languages in the class. Further we require programs to work to identify e volunteers who can be trained to work in the classroom that can provide high-quality input in children's home language(s). We added new language to the final rule under paragraph (b)(2)(iii) to reflect these realities.

Comment: Some commenters recommended we add more specificity to paragraphs (b) and (c), including on the structure of the day, the data teachers use to plan, and the types of learning experiences provided.

Response: We believe it is important to include the key elements of the teaching and learning environment so programs clearly understand the components they need to implement to have high-quality education programming. However, flexibility is also needed to allow for innovation, individualization for a class or a child, and effective implementation. Therefore, we did not incorporate the suggested revision.

Comment: Some commenters noted the term "classroom" in paragraph (c) was not inclusive of family child care terminology.

Response: We agree and revised paragraph (c) to reference "learning environments" instead of "classrooms."

Comment: Some commenters opposed or expressed concern about the proposal in paragraph (e)(1) to require an age appropriate approach that accommodates children's need to nap or rest. Some were concerned about logistical challenges such as cost, staffing, and space. Some commenters supported the proposal to promote learning through approaches to rest, noting that adequate rest is closely tied to learning and health.

Response: We made no changes to the requirements to have an intentional and age appropriate approach to children's need to nap or rest except to clarify for programs serving preschoolers, it applied for programs operating 6 or more hours per day. Though maximizing learning time is important, research shows a clear link between adequate sleep and learning.[81] [82] [83] We believe this provision will support children's health and increase the learning children can gain from other portions of the day. Moreover, most states already require center-based programs to provide naps if they operate for fewer hours than the 6-hour threshold. Therefore, many programs are already subject to a more stringent requirement.

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[83] Kurdziel, L., Duclos, K., & Spencer, R. M. (2013). Sleep spindles in midday naps enhance learning in preschool children. *Proceedings of the National Academy of Sciences, 110*(43), 17267–17272.

Comment: Some commenters opposed the proposal in paragraph (e)(2) that replaced the requirement for family style meals with an approach that was less prescriptive but retained most of the key characteristics of family style meals and ensured mealtimes were considered part of the learning day. Some commenters felt strongly that family style meals were integral to Head Start's culture. Commenters also raised concerns about eliminating an important research-based requirement because family style meals are important to teach lifelong healthy food habits and they support socialization and conversation during mealtime. Some commenters seemed concerned that family style meals would be prohibited under our proposal or that the proposal conflicted with requirements in the Child and Adult Care Food Program (CACFP).

Some commenters wrote in support of our proposal to replace the family style meal requirement with a less prescriptive proposal that focused on meals as a time for learning, socialization, and conversation. Some commenters stated that our proposal allowed for better collaboration with community partners like schools, while still retaining important parts of family style meals. Others agreed it would support intentional teacher practices, focus on conversations, learning, and socialization, and eliminate overly prescriptive requirements.

Many commenters recommended we change the provision to explicitly encourage family style meals. Some of these commenters noted that the proposal included many central characteristics of family style meals and appreciated our focus on mealtime as a learning activity. They also noted they understood the benefits of our approach since it made it easier to partner with other programs because some of the specifics of family style meals were logistically challenging for some partnerships. However, these commenters strongly recommended we add language to encourage use of family style meal so it would be consistent with CACFP and because the benefits were important.

Response: We believe it is essential that programs structure and implement meals and snacks in ways that support development and learning. Family style meal service is one effective method of accomplishing this goal. Therefore, we revised the provision in paragraph (e)(2) to make clear that programs are encouraged but not required to meet the requirement to support development and learning during meals times through the use family style meals when children are old enough for this to be developmentally appropriate practice. This is consistent with CACFP, which encourages but does not require family style meals. However, we also believe it is appropriate to not be overly prescriptive, to support partnerships, and to allow flexibility in how a program promotes learning during meals.

Comment: Some commenters expressed support for our retention of requirements in paragraph (e)(2) that children be given sufficient time to eat, should not be forced to finish their food, and that food should not be used as a reward or punishment. Some commenters wrote that we should add requirements around food activities, including retaining a requirement from the previous program standards about participating in food activities.

Response: We agree that participating in food activities can be part of good practice but think this is overly prescriptive and did not make these suggested changes.

Comment: Some commenters recommended we add requirements for physical activity, including parameters about how much time children should be physically active. They suggested requirements based on the *National Health and Safety Performance Standards: Guidelines for Out-of-Home Childcare,* including that we require at least 60 minutes of moderate to vigorous physical activity for children in Early Head Start and at least 90 minutes of moderate to vigorous physical activity for children in Head Start.

Response: We agree that physical activity is important for young children. Not only is it important for children's health, but movement and physical activity are important to children's learning and development.[84] [85] [86] Developmentally appropriate practice is clear that young children need to move and be physically active. For example, the Office of Head Start's initiative *I Am Moving I Am Learning* has been well-received by programs and helped institute healthy practices. However, we do not believe we should dictate to local programs the amount of time children should engage in such activities. To ensure that programs recognize the role of physical activity in children's learning and health, we added a new provision in paragraph (e)(4) that reads: "A program must recognize physical activity as important to learning and integrate intentional movement and physical activity into curricular activities and daily routines in ways that support health and learning. A program must not use physical activity as a reward or punishment." We believe this provision will allow local programs to implement policies appropriate to their program design and the needs of their children.

Comment: Some commenters recommended we include new requirements with specific limitations on screen time.

Response: We agree that children should have limited exposure to screen time and believe that if programs are implementing the standards in this section for nurturing, responsive, rich learning environments and experiences that effectively support strong child outcomes, screen time will, by necessity, not be available or will be appropriately limited to interactive educational activities that evidence shows support learning. However, as even the meaning of screen time is currently evolving and the research on technology use and children's learning is an emerging field, we chose not to add any specific requirements.

Section 1302.32 Curricula

This section includes requirements for the curriculum or curricula programs use. It reflects new requirements from the Act, the current role and use of curricula in the early education field, and a deeper understanding of the curriculum qualities associated with improved child outcomes. This applies to center-based and family child care programs. Curriculum requirements for home-based programs are found in § 1302.35. Some commenters were supportive of the curriculum provisions. We also received comments with concerns and suggestions that we discuss below.

Comment: Commenters were generally supportive of our curriculum provisions. They stated the section included important changes that would raise the quality of curriculum and its implementation. Commenters noted the importance of the requirements for content rich curricula, and the benefits of requiring a clear scope and sequence and integration of professional development and support for teachers. They also supported the focus on implementation fidelity and the qualities of an effective curriculum, including alignment with early learning standards.

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[84] Becker, D. R., McClelland, M. M., Loprinzi, P., & Trost, S. G. (2014). Physical activity, self-regulation, and early academic achievement in preschool children. *Early Education & Development, 25*(1), 56–70.

[85] Timmons, B. W., LeBlanc, A. G., Carson, V., Connor Gorber, S., Dillman, C., Janssen, I., . . . & Tremblay, M. S. (2012). Systematic review of physical activity and health in the early years (aged 0–4 years). *Applied Physiology, Nutrition, and Metabolism, 37*(4), 773–792.

[86] Hodges, E. A., Smith, C., Tidwell, S., & Berry, D. (2013). Promoting physical activity in preschoolers to prevent obesity: a review of the literature. *Journal of Pediatric Nursing, 28*(1), 3–19.

Response: We believe it is essential that programs intentionally review the curriculum or curricula they are using to ensure it meets each criterion in the final rule and appropriately supports children's development and learning. In some instances, we believe it will be necessary for programs to use curricula enhancements to ensure their programming is sufficiently content rich and to achieve strong child outcomes. We expect programs to be thorough in reviewing their curriculum and the professional development system that supports teachers' implementation of curriculum. For this reason, as proposed in the NPRM, programs have approximately one year after publication of this rule to implement this standard.

Comment: Some commenters recommended we include a list of acceptable curricula to ensure programs use effective ones and to help guide state pre-kindergarten curriculum choices.

Response: Development of curricula that can effectively impact child outcomes is a growing field. Programs should not just accept the publisher's word that their curriculum meets Head Start standards, but should continuously evaluate its effectiveness as part of the program management approach. We did not include a specific list of acceptable curriculum so programs have the flexibility to implement appropriate curricula for the children they enroll, supplement curricula as needed, and make changes as the field advances.

Comment: Some commenters expressed concerns about the provision in paragraph (a)(1)(iii) that requires curriculum to include an "organized developmental scope and sequence." Others supported this standard. Some commenters were concerned that "scope and sequence" would not be interpreted in a developmentally appropriate manner. Others were concerned its interpretation was not clear for infants and toddlers.

Response: We revised paragraph (a)(1)(iii) to clarify our meaning of developmental scope and sequence. This standard now reads: "has an organized developmental scope and sequence that includes plans and materials for learning experiences based on developmental progressions and how children learn." We made similar changes to the comparable provision for curricula in home-based programs in § 1302.35 for the same reasons. As part of this revision, we moved our requirement that curricula be sufficiently content-rich to promote measurable progress to paragraph (a)(1)(ii). This reorganization was for clarity; we did not change the substance.

Comment: Some commenters were concerned the curriculum requirements were not developmentally appropriate. Some were confused about narrative in the NPRM's preamble that noted that research finds that strong child outcomes for children are supported by activities that intentionally engage children in activities like math or language for 15 to 20 minutes multiple times each week.

Response: We are clear in paragraph (a)(1) that programs must implement developmentally appropriate curricula and we do not believe any of the criteria required in paragraph (a)(1) are developmentally inappropriate. Therefore, we do not need to revise this section to address this concern. Neither the proposed rule nor the final rule included any requirements about the specific amount of time teachers should spend on any particular activity. Content-rich curriculum, in which children intentionally engage in a math activity (for example), does not require children sit still or be passive recipients of rote instruction. For example, if implemented correctly, content-rich learning activities are interesting, appropriate, and engaging for children. Developmentally appropriate practice and effective intentional teaching with young children does not mean rote instruction, sitting still for lengthy periods while adults talk at them, or "drill and kill." Such teaching practices would not meet the requirements in this subpart.

Comment: Commenters supported the provisions in what were paragraphs (a)(2) and (3) that addressed professional development support for curriculum implementation and fidelity of implementation. Some commenters offered suggestions for further clarifying and strengthening the goals of these provisions.

Response: We retained the two key concepts of the provisions in paragraph (a)(2)—professional development—and paragraph (a)(3)—curriculum fidelity, but integrated and streamlined them into paragraph (a)(2) to improve clarity and implementation. Our revisions place more focus on staff support and are less compliance oriented. In paragraph (a)(2), we more clearly articulate the important requirement of supporting all teachers with support, feedback, and supervision in order to continuously improve curriculum implementation. In addition, whereas in the proposed rule, curriculum fidelity kits were likely the main way programs would comply with paragraph (a)(3), we revised paragraph (a)(2) to focus on the requirement not the method. We made similar changes to the comparable provisions for home-based programs in § 1302.35 for the same reasons.

Comment: Many commenters expressed concern or sought clarity on the provisions in paragraph (b) that proposed requirements for when programs sought to make significant adaptations to curriculum. Many commenters requested greater flexibility in curriculum requirements in paragraphs (a) and (b) so programs who serve culturally diverse communities for whom curricula have not been designed or validated. Some commenters were not clear how much adaptation would necessitate partnerships with researchers. Others thought the provision was too burdensome and unnecessary. Some supported the requirement and suggested we make it more stringent.

Response: We agree our proposal in paragraph (b) lacked sufficient clarity and flexibility. We revised paragraph (b) to require that programs that need to make significant adaptations to a curriculum or curriculum enhancement, must partner with early childhood education curriculum or content experts. For example, programs would not need to seek external expertise if they are adding a research-based curriculum supplement to an underlying curriculum in order to make it sufficiently content rich. Programs would also not need to seek external expertise if they were supplementing the curriculum's set of picture books if they were replacing them with books that reflect the diversity of culture and languages spoken in the classroom. However, a program seeking to significantly adapt a curriculum by translating major portions of it to respond to the needs of children learning more than one language would need to seek external review by a curriculum expert to ensure such translation maintained the scientifically valid characteristics of the underlying curriculum. This will ensure programs implement high-quality curricula that meet the requirements in paragraph (a). We eliminated the proposed requirement for a research evaluation of the adaptation to improve flexibility, but still encourage programs to partner with outside evaluators. To ensure accountability, paragraph (b) requires programs to assess whether the adaptation adequately facilitates progress toward meeting school readiness goals as part of the program management process described in subpart J. We believe this provision provides better clarity and strikes the right balance between flexibility and maintaining high standards for curriculum quality. We made similar changes to the comparable provision for home-based programs in § 1302.35 for the same reasons. We note that paragraph (a)(1) allows curricular enhancements and does not require the partnerships described in paragraph (b). Likewise, small changes to curricula to make them more culturally appropriate for the children being served do not require the partnerships described in paragraph (b). While not required, we encourage programs to work with a researcher or evaluator to examine their adaptations, if possible. We retain the requirement from the NPRM that programs must report curricula variations to the responsible HHS official.

Section 1302.33 Child Screenings and Assessments

This section applies screening and assessment requirements to all program options and includes significant revisions to the previous program performance standards in order to integrate advances from research, reflect best practice, and implement provisions from the Act. It includes requirements for the appropriate use of developmental screening and ongoing child assessment that are integral to high-quality programs.

Commenters supported many of the changes in this section, including the clear process for referral for formal evaluation and the updates to individualize services for children. We made changes to strengthen and clarify the provisions in this section.

Comment: Some commenters noted the importance of maintaining the 45-day requirement for developmental screenings in paragraph (a)(1), but some commenters stated the timeline for screening was too short and some stated it was too long. Some commenters noted we dropped the timeline from the previous regulation for developmental screenings in Migrant and Seasonal Head Start programs, and many commenters noted we inadvertently dropped the requirement to programs to obtain screenings instead of only explicitly completing them.

Response: The final rule retains the 45-day timeline for developmental screening. We believe it is both reasonable and important to complete screenings quickly so that individualized needs can be promptly identified. We restored the 30-calendar day timeline for Migrant and Seasonal Head Start programs to paragraph (a)(1), which is consistent with the previous regulation and was inadvertently dropped from the proposed rule. In addition, in paragraph (a)(1), we clarified that a program can meet the development screening requirement either by completing it themselves or obtaining the results from another source, and that the screening must be current.

Comment: Some commenters noted that what was paragraph (a)(2) in the NPRM for programs to adhere to a prompt timeline for referrals that they cannot control.

Response: We made revisions in paragraph (a)(3) to address these concerns. We believe it is important for programs to refer children to the local agency responsible for determining IDEA eligibility for a formal evaluation as soon as possible, and not to exceed timelines required under IDEA, but understand programs cannot control how quickly the IDEA agency completes the formal evaluation.

Comment: We received comments both in support and opposition of the proposal in what was paragraph (a)(3) in the NPRM to waive the 45-day developmental screening requirement for children with a current individualized family service plan (IFSP) or IEP. Some commenters supported the proposal and noted it was good to eliminate redundant and unnecessary screening. Some commenters opposed the provision and stated that relying only on an IFSP or IEP would lead programs to miss important information about the children they serve.

Response: We revised the final rule to remove the provision to waive the 45-day screening for children with a current IFSP or IEP. We note that developmental screenings are not overly time consuming, are not a burden for children, and agree that there is the potential for developmental issues to be missed if a program only relies on an IFSP or IEP. We believe that screenings can also serve as an important mechanism to build teacher-family partnerships, celebrate children's developmental milestones, and provide valuable information to both teachers and families on supporting children's holistic development, across settings.

Comment: Some commenters supported our proposal in paragraph (a)(5) for programs to help parents access services and support if their child has a significant delay in one or more areas of development that were likely to interfere with the child's development and school success. Some commenters suggested this was an important provision because it would ensure a specific at-risk population was better served. Some commenters supported the provision but stated that it was too vague and that further information or definitions were needed to clarify what we meant by "significant delay" and "supports and services." Some commenters also recommended referencing Section 504 and the Americans with Disabilities Act (ADA) requirements or clarity about these services being provided in the natural environment. Some commenters who supported the provision stated that these children should be counted in the program's calculation for meeting the requirement that 10 percent of children in Head Start be eligible for services under IDEA.

Many commenters were opposed to our proposal in paragraph (a)(5). They acknowledged it would be an important service but opposed it because of associated costs. Other commenters opposed the provision for reasons that included: They did not think programs had the expertise to make the decision or provide the services; they believed it was inappropriate if other specialists already deemed special education services unnecessary; or they were concerned it would undermine their partnerships with local educational agencies. Some commenters felt it was unnecessary because programs already individualize services. Some commenters agreed it could be helpful to children but that it should be a recommendation not a requirement. Other commenters who opposed the requirement requested that if we implemented the provision, the children should count toward the program's 10 percent disability enrollment requirement.

Response: We believe that when a formal assessment finds a child has a significant delay, it is important that the program work with parents to address the identified needs, even if the child is not found eligible for early intervention or special education and related services under IDEA. Therefore, the final rule retains the policy in paragraph (a)(5) but makes changes to the provision to better clarify what is and is not expected of the program. We clarified that programs are required to partner with parents to determine if needed supports and services are available through a child's health insurance and/or whether it is appropriate to provide supports for the child pursuant to Section 504 of the Rehabilitation Act if the child satisfies the definition of disability in section 705(9)(b) of the Rehabilitation Act.

A program may use Head Start funds for such services and supports when other funding is not available but the program is not required to do so. Family service, health, or other appropriate staff, together with the parents, must try to identify resources that can help provide the child with the services and supports they need. We think this clarifies what we mean by "supports and services" and did not define the term. We also note that the provision explicitly requires this determination be made with guidance from a mental health or child development professional to ensure staff with appropriate expertise guide the determination of the child's needs. We did not define "significant delay" so the mental health consultant and local experts can have appropriate flexibility.

Comment: Many commenters wrote in support of the general approach to child assessment in paragraph (b), including its research base and its clarity on using and integrating assessment information into individualization and teaching practices. However, many commenters expressed concern about the term "standardized and structured assessment" in paragraph (b)(1) and sought greater clarity on its meaning.

Response: We added language to paragraph (b)(1) to clarify that the standardized and structured assessments may be "observation-based or direct."

Comment: Some commenters recommended we add requirements about the frequency of assessments or made other suggestions for paragraph (b), such as how the data are reported.

Response: We did not revise paragraph (b) to include requirements about the frequency of assessments because we believe those determinations are best made at the local level. However, we made small changes in paragraph (b)(2) to further strengthen how programs use assessments. Specifically, paragraph (b)(2) was revised to require program "regularly" use assessment and other information to support individualized learning and that such assessment data be used to "inform" strategies for individualization.

Comment: Some commenters were unclear about the need to assess DLLs in multiple languages if they are proficient in English, as proposed in paragraph (c)(2). Some recommended that DLLs only be assessed in their non-English language if they struggle with English. Some commenters stated that assessment in both languages should not be required for program participation and asked whether programs will seek parental input or consent for screenings and assessments in both languages.

Response: Assessing the language development of a DLL child in both English and his/her home language provides a more complete picture of the child's language development, including potential strengths or concerns, even if the child is proficient in English. Additionally, as stated in § 1302.34(b)(6), program staff must inform parents and family members about the purposes and results of screenings and assessments and discuss children's progress.

Comment: Commenters were concerned with the feasibility of assessing DLLs in their home language as proposed in paragraph (c)(2). Commenters raised concerns such as: lack of valid, reliable assessments in less common languages; feasibility of having interpreters for all languages; and burden on staff to assess children in both languages. Some commenters requested clarification, such as if it is acceptable for an English-speaking staff person to use a Spanish interpreter to conduct assessments with DLLs and, for assessments conducted in both languages, if teachers should record the higher of the two scores.

Response: We strongly believe that programs should assess DLLs in their home language with valid, reliable assessments, when feasible. While Spanish is the home language of most DLLs in Head Start, we recognize that there are over 140 other languages spoken by Head Start children and that valid, reliable assessments are not available in every language spoken by children in Head Start. We revised paragraph (c)(2)(ii) and added new language at paragraph (c)(2)(iii) in the final rule to reflect this reality including mechanisms that support accurate and appropriate assessment processes. We also revised paragraph (c)(3) to acknowledge when interpreters may be necessary to work in conjunction with qualified staff that do not speak the language. Finally in paragraph (c)(4) we clarified that only in instances where an interpreter and qualified staff are not available can screenings and assessments be done in English, but it is particularly important that programs gather and use other information and structured observations over time about the child development, including information from the family about home language use. Assessments with DLLs should be conducted with the same frequency as that for all children—as noted in paragraph (b)(1), assessments must be conducted with sufficient frequency to allow for individualization within the program year.

Comment: Some commenters were concerned that requirements for serving DLLs might not support parental choice, including the requirement in paragraph (b)(2) to assess children in both languages, and the focus on exposure to English for infants and toddlers in § 1302.31(b)(2)(i).

Response: We believe assessing children's language skills in both English and their home language is necessary to accurately capture DLL children's language development. Additionally, the Act requires Head Start programs support the acquisition of English for DLL children.

§ 1302.34 Parent and Family Engagement in Education and Child Development Services

This section includes provisions to ensure that center-based and family child care programs structure their education services to recognize parents' important roles in their child's education. It primarily reflects the previous requirements replaced by the final rule but reorganizes them for better clarity and implementation.

Many commenters expressed an overarching concern that the proposed rule diminished the role of the parents, though commenters generally supported this section and noted it retained the important philosophy that parents are children's first and most important teachers. Some commenters also recommended changes, some of which we felt were too prescriptive or unnecessary to support best practice. Other comments are discussed below.

Comment: Some commenters recommended changes to further clarify the important role of parents and suggested greater alignment with the Parent Family and Community Engagement Framework.

Response: We revised this section to clarify and strengthen the standards. For example, the section heading has been changed from "Parent involvement" to "Parent and family engagement in education and child development services" to better reflect the intent of this section and align the work programs have done with the Parent, Family, and Community Engagement Framework. In addition, changes were made in paragraph (a) to better reflect parents' central role in children's education. We added a new provision in paragraph (b)(2) to strengthen the engagement between teaching staff and parent. In addition, we made changes in paragraphs (b)(4), (6), and (7) to better distinguish which engagement activities are appropriate for parents as opposed to families.

Comment: Some commenters stated that we required too many home visits, and others suggested we require more home visits. Some commenters opposed the requirement in paragraph (b)(7) for teachers to complete a home visit before the start of the program year, if possible, while others supported it.

Response: In response to comments seeking some clarification, we made a few small structural changes to the provision that is now found in paragraph (b)(7) to clarify the home visit requirement. However, we did not revise the number of required teacher home visits. Further, we note that paragraph (b)(7) states that one visit should take place before the program year begins ''if feasible.'' We believe that home visits before the start of the program year reflects best practice but that sufficient flexibility is provided when it truly is not feasible. As before, teachers can do more than two home visits if they feel that is appropriate.

Comment: Some commenters recommended combining the provisions in this section with those in § 1302.51.

Response: We agree that both this section and § 1302.51 address activities to engage parents and families in their children's learning. However, we did not combine the sections because this section specifically addresses services and philosophies related to children's educational services and § 1302.51 includes parent services and are better organized in the parent engagement subpart.

Section 1302.35 Education in Home-Based Programs

This section includes the requirements for education services in home-based programs. It codifies and builds upon the guidance and technical assistance we provided to home-based programs for many years. We discuss comments and changes we made to the proposed rule below.

Comment: Some commenters supported the use of research or evidenced-based home visiting curriculum, the use of promising practices, and recommended we specify particular home visiting programs or curricula or asked for clarifications about the requirement.

Response: We believe the use of a research-based home visiting curriculum is critical to ensuring home-based services improve child and family outcomes. We did not revise the section to require a particular curriculum for serving children in the home-based program because we believe programs should have local flexibility to select a curriculum that best meets the needs of the children and families they serve. We clarified the language around adaptations of curricula in the same way as in § 1302.32 for center-based and family child care programs.

Comment: Some commenters suggested we include language that clearly states home visits are to help parents understand their child's development and to support responsive interactions between parent and child. Some commenters further requested clarification about how the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* applies to home-based because it does not include family goals.

Response: We agree that home visits must reflect the critical role of helping parents support the early learning and development of their children. Therefore, we revised paragraph (b)(1) to clarify that home visitors must be able to effectively communicate with parents directly or through an interpreter. In addition, we reordered the home-based education section to put the parent and the home-based experiences in paragraph (c) prior to the discussion of curriculum now found in paragraph (d), to emphasize the central role of parents in successful home-based services. We believe this addresses the comments and that further revision is not necessary. Further, the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* describes what children ages birth to five should know and do. We have the same expectations for all children enrolled in any Head Start option.

Comment: Many commenters suggested that we require components of the Parent, Family, and Community Engagement Framework (PFCEF) to be included in the home visit experiences in what was paragraph (d) and is now paragraph (c).

Response: Programs are required to use the PFCEF as part of their family engagement services, which are already required in paragraph (b)(4). Therefore, we did not make this revision.

Section 1302.36 Tribal Language Preservation and Revitalization

This section provides support for programs serving American Indian and Alaska Native children that wish to or are already engaging in tribal language revitalization efforts. We added this as a new section based on reviewer comments about our inconsistent inclusion and meaning of the phrase ''Native language'' in the proposed standards in the NPRM.

Comment: Some commenters expressed concern about the inconsistency of the inclusion of ''Native language'' for American Indian and Alaska Native children and requested clarity on the intent of these provisions in §§ 1302.31 and 1302.35.

Response: We revised the language in §§ 1302.31 and 1302.35 to clarify the intent of these provisions with respect to American Indian and Alaska Native children. Additionally, we added this new section to clarify that programs serving American Indian and Alaska Native children may choose to engage in efforts to preserve, revitalize, restore, or maintain the tribal language(s) for these children.

Health Program Services; Subpart D

In this subpart, we updated program performance standards related to health, nutrition, mental health, and safety. We retained the core health services from the previous program performance standards, including screening, ongoing care and follow-up care both because the Act clearly links health, mental health, and nutritional services as important supports to foster children's school readiness and because research demonstrates a strong link between child health, school readiness, and long-term outcomes.[87] [88] [89] We further strengthened the requirements with an emphasis on oral health and parent education in health issues. We also updated the mental health requirements to reflect best practice, to ensure programs use mental health services to improve classroom management, and to support staff in effectively addressing challenging behaviors. We also streamlined program performance standards to make it easier for programs to find what they need and to implement what we require. We received many comments on this subpart. Commenters generally supported our reorganization and streamlined requirements. Some noted their support for our continued emphasis on health services as central to Head Start. Many commenters offered recommendations for additional changes. In response to comments, we made technical changes, clarified requirements, and further strengthened health, nutrition, and mental health services. We also improved family support services and strengthened and clarified safety practices. We discuss comments and our responses below.

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[87] Currie, J.M. (2005). Health disparities and gaps in school readiness. *The Future of Children, 15*(1), 117–138.

[88] Janus, M., & Duku, E. (2007). The school entry gap: Socioeconomic, family, and health factors associated with children's school readiness to learn. *Early Education and Development, 18*(3), 375–403.

[89] Bruner, C. (2009). Connecting child health and school readiness. (Issue Brief No. 9). Denver, CO: The Colorado Trust.

General Comments

Comment: Some commenters were concerned we diminished the importance of health services in Head Start.

Response: We do not believe we diminished the importance of health services in Head Start. The rule is clear that programs are required to promote the health and well-being of all children in Head Start. We believe this is central to Head Start's mission of helping children succeed in school and in life. The rule clearly articulates the many health services programs must provide and allows programs better flexibility to focus on improved delivery of health and well-being services instead of process-laden requirements.

Comment: Some commenters recommended we replace the word "dental" with "oral" throughout the rule to reflect current scientific and clinical terminology.

Response: We agree "oral" is a more appropriate description than "dental." Therefore, we replaced the word "dental" with "oral" throughout the regulation.

Section 1302.40 Purpose

In this section, we outline the overall goal of this subpart, which is to ensure programs provide high-quality health, mental health, and nutrition services that support each child's growth and school readiness. To improve clarity, we moved the requirement for programs to establish and maintain a Health Services Advisory Committee from subpart E to this section.

Comment: Some commenters suggested we include oral health in the list of health services included under this section. Other commenters recommended we include the word "culturally" in the description of appropriate services.

Response: We agree oral health is an important element of overall health and might not automatically be recognized as included under health. So, we added "oral health" to the list of health services. We also agree health practices need to be culturally appropriate and revised paragraph (a) to improve clarity about service delivery.

Section 1302.41 Collaboration and Communication With Parents

This section requires programs collaborate and communicate with parents about their children's health in a linguistically and culturally appropriate manner and communicate with them about health needs and concerns in a timely manner. It also includes program requirements for advance authorization from parents and for sharing policies for health emergencies. We received some comments on this section.

Comment: We received some comments requesting clarification on communication and collaboration with parents. For example, commenters noted that an example offered in the NPRM preamble did not appear in the regulation text. Other commenters asked which "health emergency policies" referenced in paragraph (b)(2) programs must share with parents.

Response: The preamble in the NPRM provided explanation and rationale for the proposed requirements. We offered examples as guidance to make the rule more accessible to readers. We did not revise the requirement about sharing policies for health emergencies because we think it is appropriately described. Most programs share their health emergency policies with parents through a parent handbook or other vehicle.

Section 1302.42 Child Health Status and Care

This section includes requirements for programs to determine children's source of care, to support parents in ensuring children are up-to-date for preventive and primary medical and oral health care, and to support parents to ensure children receive ongoing necessary care. It also requires programs to determine if children have health insurance and supports families in accessing health insurance if they do not. It also includes requirements for extended follow-up care where appropriate and clarifies use of program funds for medical and oral health services. Commenters generally supported this section but also requested clarification and offered additional suggestions. We address these comments below.

Comment: We received many comments about the timelines in paragraphs (a) and (b) that describe requirements for determining whether a child has an ongoing source of health care and insurance coverage, to assist families in accessing care and health coverage, and to determine if children are up-to-date on preventive and primary medical and oral health care. Some commenters stated that the 30-day and 90-day timelines in paragraphs (a) and (b) were too long and would result in delayed services. Some commenters stated the 30-day timeline in paragraph (a)(1) was too short. Many commenters requested additional clarification on the timelines. For example, many commenters requested more specificity about what we meant by "as quickly as possible" in paragraph (a)(2). Some commenters suggested we clarify the definition for "program entry" to distinguish it from "enrollment." They stated that the perceived distinction between the two terms could result in unintended consequences, such as programs delaying child enrollment because they cannot obtain required health information before children actually attend the program.

Response: We retained the 30-day and 90-day timelines from the previous standards, which we believe are appropriate to ensure children's needs are addressed in a timely manner and have not presented problems for most programs to meet. However, to improve clarity about when the timelines begin, we replaced the phrase, "from the child's enrollment" with "after the child first attends the program or, for the home-based program option, receives a home visit" in paragraphs (a)(1), (b)(1), (b)(2) and (b)(3) to clarify when requirements must be met.

Comment: Some commenters recommended we revise paragraph (a)(2) to recognize the unique role that Indian Health Services plays for many children enrolled in tribal Head Start programs.

Response: We acknowledge the role Indian Health Services plays for children enrolled in American Indian Alaska Native Head Start programs. However, we did not think it was necessary to provide additional clarity in paragraph (a)(2). Paragraph (a) clearly does not exclude any source of continuous and accessible health care.

Comment: Some commenters recommended changes or requested more clarity to the requirements in paragraph (b)(1)(i) to determine if children are up-to-date on preventive and primary care. For example, some commenters requested we specifically include oral health care services. Some commenters suggested we waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) requirement for blood lead testing because of concerns that local doctors refuse to do blood lead tests for children who are at low risk based on a lead risk assessment. Others suggested we allow programs to substitute a lead risk assessment in lieu of blood lead testing. Some commenters requested more clarity about the meaning of "health care professional" as it relates to oral health. Others requested more clarity about the qualifications of health care professionals.

Response: We revised paragraph (b)(1)(i) to improve clarity. We amended this paragraph to include "dental periodicity schedule" to clarify programs must determine whether the child is up-to-date on both medical health and oral health care. We agree that our use of the term "health care professional" to apply to both health and oral health was confusing. So, we amended this provision to include "oral health care professional" as well as "health care professional." We did not specify qualifications for health care professionals, because state requirements vary. We expect programs to ensure that health and oral health professionals are qualified in their respective areas per state requirements. We did not make revisions to the requirements related to EPSDT because we do not have the authority to promulgate a regulation that contradicts how states implement EPSDT, especially in light of the potential serious health consequences of elevated lead levels.

Comment: Some commenters stated that paragraphs (b)(1)(ii) and (iii) suggested parents were not capable of or bore no responsibility to get their children up to date on immunizations. They believed the requirement would force programs to undermine the role of parents when they provide this service.

Response: It was not our intent to undermine the role of parents in getting children up-to-date with preventive and primary medical and oral health care. We consolidated what were paragraphs (b)(1)(ii) and (iii) in the NPRM into paragraph (b)(1)(ii) and revised the language to more clearly articulate our intent. We expect programs to help parents, as necessary, in their efforts to ensure their children are up-to-date with preventive and primary care. For those children who are not up to date, paragraph (b)(1)(ii) requires that programs must assist parents to make arrangements to bring their children up to date and to directly facilitate health services only with parental consent.

Comment: Some commenters were concerned that paragraph (b)(2) required programs to conduct all hearing and vision screenings, rather than accept screening results from another source. In addition, commenters suggested that children should be screened for "mental and physical trauma," as well as hearing and vision.

Response: We revised paragraph (b)(2) to clarify that programs must either conduct or obtain hearing and vision screenings. We did not make revisions to specifically include screening for mental and physical trauma. Local programs may, with parent consent, implement such screening as indicated, particularly if they serve populations with known or likely exposure to trauma.

Comment: Some commenters suggested revisions to paragraph (b)(4) that requires a program to identify children's nutritional health needs and describes specific information they must take into account. For example, some commenters opposed requirements to collect so much specific health information because it was an unhelpful "paper chase" and unnecessarily burdensome since health care providers already collect this data and provide follow up as necessary. Some commenters opposed our requirements that programs collect hematocrit or hemoglobin for each child. Some commenters suggested we require programs to collect additional information about children's health status, such as sweetened beverage consumption, physical activity, screen time levels, and consumption of healthy foods such as whole grains, fruits, and vegetables. Some commenters asked for clarification about what follow-up was necessary based on the health information. Some commenters objected to the requirement accounting for all children's body max index (BMI) when BMI is not generally used for children under age two. Other commenters expressed concern about whether Head Start staff are qualified to interpret BMI and suggested programs with concerns about children's weight, BMI, or growth refer families to their physicians for further assessment. Commenters requested clarification, including a timeline to identify nutrition needs.

Response: We believe it is appropriate to require programs collect some information about each child's nutritional health status to help meet the individual needs of children. However, we revised paragraph (b)(4) so that rather than requiring programs to collect and track data on all children, many of whom would fall within typical or acceptable ranges, we require programs to identify each child's nutritional health needs, taking into account available health information, including the child's health records, and family and staff concerns. In addition, in paragraph (c), we required programs to work with parents to ensure children obtain necessary referral, follow up appointments, and treatments. Programs may collect height and weight data directly as a means to more regularly track growth and as part of the required periodic observations or use other appropriate strategies for new or recurring concerns. We also revised paragraph (d) to include examples of how programs would use health information that may affect children's development, learning, or behavior.

Comment: Commenters suggested we revise paragraph (c)(3) to state topical fluoride or varnish can be used for all children, not just for those that live in areas where the water is not fluoridated.

Response: We revised paragraph (c)(3) to clarify programs must provide oral health preventive care for all children including, access to topical fluoride treatments and, as indicated, fluoride supplements.

Comment: Some commenters requested we require programs to provide diapers and formula for infants and toddlers during the portion of the day they attend the program.

Response: In paragraph (e)(1), we codified a long-standing expectation that programs must provide formula and diapers as needed by children during the time they attend the program.

Section 1302.43 Oral Health Practices

In this section, we require programs to promote effective oral health hygiene with daily tooth brushing. Research demonstrates a link between oral health, dental pain, and children's attendance in preschool programs, as well as their ability to effectively engage in class activities.[90] [91] [92] [93] We discuss the comments we received on this section below.

Comment: Commenters offered a number of suggestions for this section. Some recommended we change the title of this section to "Tooth brushing and other evidence or best practice based preventive oral health practices." Some commenters recommended we include greater specificity. For example, some recommended we include requirements for cleaning infant gums, to use toothpaste that contains fluoride, to implement tooth brushing as soon as a child's first tooth emerges, or to ensure children brush their teeth two times per day, for two minutes each time.

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[90] Abanto, J., Carvalho, T. S., Mendes, F. M., Wanderley, M. T., Bönecker, M. and Raggio, D. P. (2011), Impact of oral diseases and disorders on oral health-related quality of life of preschool children. *Community Dentistry and Oral Epidemiology, 39,* 105–114. doi: 10.1111/j.1600–0528.2010.00580.x.

[91] U.S. General Accounting Office. (2000). *Oral Health: Dental Disease Is a Chronic Problem Among Low Income and Vulnerable Populations.* Washington, DC: General Accounting Office.

[92] Schechter N. 2000. The impact of acute and chronic dental pain on child development. *Journal of the Southeastern Society of Pediatric Dentistry 6*(2), 16.

[93] Altarum Institute. 2007. Issue Brief: *Oral Health Is Critical to the School Readiness of Children in Washington, DC.* Washington, DC: Altarum Institute.

Response: We revised the title of this section from "Tooth brushing" to "Oral health practices" to better reflect the connection between tooth brushing and oral health status. We also revised this section to require that all children with teeth, not just those age one or older, have their teeth brushed at least once per day with toothpaste that contains fluoride. We did not make further revisions to this section because we did not think further specificity was appropriate or supported by strong evidence.

Section 1302.44 Child Nutrition

This section details program performance standards for Head Start programs to meet each child's nutritional requirements and feeding needs. This section includes nutrition service requirements, including how much food should be offered and requirements for supporting breastfeeding. It also includes requirements about use of funds. Nutrition is one of the founding principles of Head Start programs. Good nutrition supports children's ability to grow, develop, and achieve and maintain a healthy weight. Commenters suggested revisions and sought clarification. Based on comments we received, we made some changes to improve clarity and further strengthen requirements. We address comments below.

Comment: Some commenters recommended we specify in paragraph (a)(1) that nutrition services must be culturally and developmentally appropriate to ensure they respond to the needs of enrolled children.

Response: We agree and made this revision.

Comment: Some commenters recommended we add additional requirements to paragraph (a)(2). For example, some commenters suggested we require programs to make drinking water available to children. They stated that if children were able to satisfy thirst with water, they may be less likely to consume large amounts of sugar sweetened beverages. Other comments suggested we require programs to serve a varied diet with an emphasis on fruits, vegetables, and whole grains rather than meet a proportion of children's daily nutritional needs.

Response: We revised this section to add a new requirement at paragraph (a)(2)(ix) to require programs make safe drinking water available to children during the program day. We did not make revisions to emphasize fruits, vegetables, and whole grains because we think the requirement that programs meet the nutritional needs of children and adhere with CACFP requirements on meal patterns is sufficiently prescriptive.

Comment: We received some comments about how our requirements in this section interact with CACFP requirements. For example, some commenters requested we remove the requirement in paragraph (a)(2)(iii) about food being high in nutrients and low in fat, sugar, and salt because it is redundant with CACFP. Some other commenters expressed concern or sought clarification about or exemption from CACFP requirements because of burden and cost.

Response: We did not revise paragraph (a)(2)(iii) because we believe it is necessary to emphasize the importance of healthy food that is high in nutrients and low in salt, fat and sugar over and above CACFP requirements regarding the nutrition content of food. We did not revise paragraph (a)(1)(iv) because we think it is sufficiently clear. In addition, we note that we require programs to use reimbursement from CACFP, unless, as might occur in a home-based option, CACFP is not available. In that case, programs may use Head Start or Early Head Start funds for allowable food costs as we state in paragraph (b). We have no authority to change CACFP requirements and made no revisions.

Comment: Commenters suggested we retain the provision from the previous program performance standards that required programs to involve parents and appropriate community agencies in planning, implementing, and evaluating the program's nutrition services.

Response: We did not retain the previous standard that programs engage parents and the community in nutrition services. While we think this can be a valuable method to ensure cultural appropriateness and respond to local nutrition related issues, we recognize it may be difficult for some programs to regularly do this. We encourage programs to maintain this practice as much as they can, but we want to provide local flexibility to identify the approach.

Comment: Some commenters indicated that the word "appropriate" in paragraph (a)(2)(vii) that modifies snacks could vary widely in interpretation and suggested we replace "appropriate" with "healthy."

Response: We agree this requirement is clearer if we indicate snacks and meals should be "healthy" and revised the paragraph accordingly.

Comment: We received comments about our requirement to promote breastfeeding in paragraph (a)(2)(viii). Commenters were generally supportive of our focus on breastfeeding. Some commenters recommended we require programs to train staff on how to properly handle and store breast milk. Other commenters recommended we require programs to either ensure staff complete lactation counselor training or provide referrals to lactation counselors or consultants. Others asked us to clarify whether programs must have breastfeeding rooms in each center.

Response: We did not think it was necessary to add a requirement for programs to train staff on how to properly handle and store breast milk because we think that is unnecessarily prescriptive in detailing how a program must meet the requirement that they properly store and handle breast milk. Many programs will find state licensing already requires this. We also did not require programs to ensure staff complete lactation counselor training. However, we amended paragraph (a)(2)(viii) to require programs provide referrals to lactation consultants or counselors if necessary. Finally, neither the NPRM nor the final rule required programs to have separate rooms for breastfeeding in each center. Programs may meet the requirement in § 1302.44(a)(2)(viii) to promote breastfeeding with a designated private area with a comfortable chair, an outlet for a pump, and access to a sink for hand washing to accommodate the needs of mothers who breastfeed or pump milk.

Section 1302.45 Child Mental Health and Social and Emotional Well-Being

This section includes the requirements for services programs must provide related to child mental health and the support of children's social and emotional well-being. Early childhood mental health and healthy social and emotional well-being has been clearly linked to children's school readiness outcomes. Research estimates between 9 percent and 14 percent of young children experience mental health or social and emotional issues that negatively impact their development.[94] The standards described in this section support programs in creating a culture that promotes positive mental health and social and emotional well-being, including supporting positive staff-child interactions and parental knowledge of mental health. Research also demonstrates that the use of mental health consultation services has distinct benefits, including improved child behavior, staff job satisfaction, and overall effectiveness of early childhood programs.[95] [96] [97] Therefore, this section also includes specific requirements for what mental health consultants must do to assist programs, staff, and parents.

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[94] Brauner, C. B., & Stephen, B. C. (2006). Estimating the prevalence of early childhood serious emotional/behavioral disorder. *Public Health Reports, 121,* 303–310.

In general, commenters supported strengthening mental health consultation in Head Start, but suggested ways to improve the standards to ensure a clear understanding of the importance of mental health, the qualifications of a mental health consultant, and the role that the mental health consultant plays in improving programs' ability to address mental health problems, including challenging behaviors. We address these and other comments below and describe changes we made to this section to ensure that programs have the tools to successfully promote the mental health and social and emotional well-being of all children.

Comment: Commenters suggested we refer to social-emotional well-being rather than "child mental health" to reduce the prejudice and discrimination around mental health services and improve parent and staff understanding of what mental health means for children.

Response: We agree and revised the title of this section as well as the requirements throughout to more accurately mirror how the field of early childhood discusses children's mental health and behavior by more broadly defining child mental health and social and emotional well-being.

Comment: Commenters requested clarification about who can serve as mental health consultants and the role of mental health consultants in the program. For example, commenters asked about the necessary qualifications of mental health consultants and the amount of time mental health consultants must spend in the program. Commenters also noted a shortage of mental health consultants who are licensed, particularly in rural and tribal areas, and suggested sharing best practice information about effective mental health consultation in such programs. Some commenters misinterpreted this section to remove requirements for programs to use mental health consultants and were in favor of only utilizing mental health consultants on an as-needed basis. Other commenters suggested that additional funds would be needed to implement these standards.

Response: We agree that it is important for programs to understand the importance of mental health and the role of mental health consultants in promoting the well-being of Head Start children. We revised this section to include that programs must ensure mental health consultants assist the program, staff and parents and clarified how programs must support a culture of promoting children's mental health and social and emotional well-being. We clarified the qualifications of mental health consultants in § 1302.91(e)(8)(ii). We understand that access to mental health consultants, particularly those with knowledge and experience serving young children, may not be available in all communities, and that there may be a particular struggle in tribal and rural areas, but we believe access to mental health consultants in all programs is critically important. In order to acknowledge this difficulty, we only require knowledge and experience working with young children if consultants with this knowledge and experience are available in the community.

To address the level of utilization of mental health consultants, we revised paragraph (a)(2) to reinstate the requirement from the previous regulation that a program must "secure mental health consultation services on a schedule of sufficient and consistent frequency." We also clarified that programs must ensure that mental health consultants are available to partner with staff and families in a timely and effective manner. Additionally, to improve clarity, we added a new paragraph (b)(6) to reference the use of mental health consultants as required in § 1302.17. While we understand the concerns some commenters describe related to cost, Head Start has a long-standing history of using mental health consultants who are certified and licensed and we expect programs to meet these requirements within their existing budgets and may use a variety of strategies, including the use of technology, when capacity is an issue.

Comment: Some commenters recommended that the standards be revised to require parental consent for consultation.

Response: To help normalize the mental health consultation process and reduce prejudice and discrimination around use of mental health consultants, we revised paragraph (a)(3) to require programs to obtain parental consent for mental health consultation services when they enroll children in the program.

Comment: Commenters suggested we add specific strategies for addressing mental health issues and challenging behaviors, including home visits, Applied Behavior Analysis, and trauma-informed care. Some commenters suggested we require programs track and evaluate mental and behavioral health practices in programs.

Response: While we agree that these strategies can be effective in supporting children with behavioral and mental health problems, we think it is important to give programs flexibility to address individual child needs in the most appropriate way. Therefore, we do not prescribe specific practices or strategies, but have revised paragraph (b)(1) to reflect the concept in paragraph (a) that programs must implement strategies to identify and support children with mental health and social and emotional concerns and their families.

Comment: Some commenters recommended the inclusion of mental health services within the context of home visiting or family child care options so that these services will be more effectively integrated throughout various program settings.

Response: We agree that mental health consultants should support staff in all Head Start program models and revised paragraphs (b)(2) and (3) to clarify our intent.

Comment: Commenters further suggested that internalizing or withdrawn behaviors should be explicitly referenced throughout the requirements to broaden the focus of child mental health beyond behaviors that can disrupt classes. Commenters also noted these problems need to be both identified as well as supported.

Response: We also added paragraph (b)(4) to explicitly include both internalizing and externalizing problems as issues for mental health consultants to assist staff to address.

Comment: Commenters stated that this section does not reflect the important role of parents and parental mental health.

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[95] Gilliam, W.S., & Golan, S. (2006). Preschool and child care expulsion and suspension: Rates and predictors in one state. *Infants and Young Children, 19*(3), 228–245.

[96] Perry, D. F., Dunne, M. C., McFadden, L., & Campbell, D. (2008). Reducing the risk for preschool expulsion: Mental health consultation for young children with challenging behaviors. *Journal of Child and Family Studies, 17*(1), 44–54.

[97] Brennan, E. M., Bradley, J. R., Allen, M. D., & Perry, D. F. (2008). The evidence base for mental health consultation in early childhood settings: Research synthesis addressing staff and program outcomes. *Early Education and Development, 19*(6), 982–1022.

Response: We agree that parents are critical to the promotion of child mental health and did not intend for the requirements to exclude them. We have added paragraph (b)(5) to explicitly include parents.

Section 1302.46 Family Support Services for Health, Nutrition, and Mental Health

This section includes the requirements that address health education and support services that programs must deliver to families. It consolidated requirements from the previous rule to improve clarity and transparency. This section highlights the critical importance of parental health literacy, which has been linked to the health and long-term outcomes of young children.[98] [99] Commenters supported this section and our reorganization. Commenters also offered suggestions to expand, reduce, and reorganize the requirements. We discuss comments and our responses below.

Comment: We received some comments with broad suggestions for this section. For example, commenters suggested we include a specific emphasis on father involvement. Commenters expressed concerns that staff do not have time to comply with the section's requirements and that the requirements are too broad. Others recommended we move this section to follow § 1302.41.

Response: We did not make revisions to address these comments. This section addresses parents, which is defined to encompass mothers and fathers. Strategies to promote father engagement are included in subpart E. In addition, we believe these requirements are critical to supporting child and family outcomes and are an essential part of Head Start's comprehensive two-generation approach. Finally, we think the organization of subpart D clearly conveys requirements and did not revise the order of the sections.

Comment: Some commenters suggested revisions to increase the emphasis on health literacy and parent collaboration.

Response: We made slight revisions to paragraph (a), which we believe appropriately emphasizes parent collaboration, including for individuals with low health literacy.

Comment: Some commenters recommended we expand services in paragraphs (b)(1) related to nutrition, breastfeeding, tobacco, lead exposure, safe sleep and mental health. Some expressed concern that the requirements did not appropriately reflect the important role of parents and parental mental health and suggested revisions. They also recommended we revise our terminology about mental health to more clearly indicate the breadth of issues that should be addressed.

Response: We agree and revised these three paragraphs to better clarify the topics on which programs must offer to collaborate with parents to include health and developmental consequences of tobacco and lead exposure, safe sleep, healthy eating and the negative health consequences of sugar-sweetened beverages; breastfeeding support and treatment options for parental mental health or substance abuse problems; and more broadly defined child mental health and social and emotional well-being.

Comment: Some commenters recommended we include requirements to specifically assist children and families accessing health insurance for which they are eligible.

Response: We agree that programs play an important role in assisting families who need health insurance. We revised paragraph (b)(2)(i) to specify that programs provide information about public and private health insurance and designated enrollment periods.

Section 1302.47 Safety Practices

This section includes the requirements for strong safety practices and procedures that will ensure the health and safety of all children. Basic health and safety practices are essential to ensure high-quality care. In some instances, we moved away from prescribing extensive detail when it is unnecessary to maintain a high standard of safety. Instead, we allow programs flexibility to adjust their policies and procedures according to the most up to date information about how to keep children safe. To ensure programs are equipped with adequate instruction on how to keep children safe at all times, we encourage programs to consult a new ACF resource called *Caring for Our Children Basics* (*Basics*).[100] The section includes health and safety requirements for facilities, equipment, materials, background checks, safety training, safety practices, administrative safety procedures, and disaster preparedness plans. These recommendations were informed by research and best practice. We received many comments on this section including suggestions to expand, reduce, and clarify requirements. We address the comments we received on this section below.

Comment: Many commenters appreciated our focus on health and safety systems instead of extensive checklists and recommended monitoring protocols reflect this approach.

Response: We agree that the systems approach reflected in this rule is preferable to a checklist approach and have made a number of small changes to further support the systems approach, including in paragraphs (b)(1)(ix) and (b)(2)(v) adding that programs must keep facilities and materials safe through an ongoing system of preventive maintenance. This systems approach will also be reflected in monitoring in the future.

Comment: Some commenters recommended we rely on state licensing for health and safety standards and not include different health and safety standards.

Response: Many states have stringent health and safety regulations, but some do not. In addition, not all Head Start programs are state licensed. Therefore, we retained this section in the final rule; however, we have made some language changes to align the health and safety training for staff to the health and safety requirements in the CCDBG Act. This will relieve the burden of different or conflicting licensing standards.

Comment: Some commenters addressed our provision in paragraph (a) that programs should consult *Caring for our Children Basics* for additional information to develop and implement adequate safety policies and practices detailed further in the subpart. Some commenters appreciated the flexibility we afforded programs under this section though noted that reduced specificity may compel programs to consult other authorities. Some commenters supported our inclusion of *Caring for Our Children Basics* and some suggested we require the specifics recommendations from *Basics* and include them in the regulation. Some commenters objected to the requirement and offered alternatives. For example, some commenters recommended we require programs to either "follow" *Basics* or "consult" *Basics* so our intent is clearer. Some commenters stated the requirements in *Basics* were unnecessarily high and costly. Other commenters requested additional clarification or expressed concern about what would happen if there were inconsistencies between *Basics* and state or local standards. Some seemed confused about the difference between *Caring for Our Children* and *Caring for Our Children Basics* or pointed out differences between the two documents. Some commenters were concerned about potential inconsistencies if *Basics* is updated more frequently than Head Start Program Performance Standards. Some commenters were concerned we would find programs to be out of compliance if they failed to meet all the recommendations included under *Basics*.

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[98] Herman, A., & Jackson, P. (2011). Empowering low-income parents with skills to reduce excess pediatric emergency room and clinic visits through a tailored low literacy training intervention. *Journal of Health Communications, 15*(8), 895–910.

[99] Dewalt, D.A., & Hink, A., (2009). Health Literacy and Child Health Outcomes: A Systematic Review of the Literature. *Pediatrics, 124*(3), 265–274.

[100] *https://eclkc.ohs.acf.hhs.gov/hslc/tta-system/health/docs/caring-for-our-children-basics.pdf.*

Response: We believe our reference to *Basics* will help clarify minimum health and safety expectations across early childhood settings. Many programs already exceed what *Caring for Our Children Basics* recommends as best practice. Other programs may need guidance in establishing their policies, procedures and systems and *Basics* will be a useful resource guide for these programs. Furthermore, *Basics* represents a uniform set of health and safety standards and provides specific guidance to assist programs in achieving the standards identified in this regulation. We believe *Basics* will be an important resource for programs and useful tool for achieving consistency across programs. Therefore, we retained our requirement in paragraph (a) that encourages programs to consult *Basics in developing their safety standards and training.*

Comment: We received comments requesting clarification on the introductory text in paragraph (b) and paragraph (b)(1). For example, a commenter suggested we delete "at a minimum" in the introductory text in paragraph (b) to improve clarity. In addition, some commenters suggested we require family child care providers store guns and ammunition so children cannot readily access them. They also recommended we require programs to train staff on safe gun and ammunition storage procedures. Other commenters noted we omitted food preparation from paragraph (b)(1)(viii). Others suggested we require smoke-free environments and promote smoke-free environments for children to families and other caregivers.

Response: We agree the placement of "at a minimum" in the introductory text in paragraph (b) was confusing and moved it to paragraphs (b)(1), (2), (4), (5), (6), and (7) to improve clarity. We did not include revisions on gun safety because we think the requirement in paragraph (b)(1)(vii) that states facilities must be free from guns or firearms that are accessible to children is sufficient. Local programs may elect to provide training on storage safety but we did not require it. We revised paragraph (b)(1)(viii) to clarify that facilities have separate toileting and diapering areas from areas for food preparation. This reflects an important basic requirement from the previous program standards. We agree smoke-free environments are important. We did not make revisions to address this comment because paragraph (b)(1) already requires facilities be free from pollutants and we prohibit smoking in all Head Start facilities under the terms of grant awards.

Comment: We received comments about our requirement in paragraph (b)(2) that all equipment and materials meet standards set by the Consumer Product Safety Commission (CPSC) and the American Society for Testing and Materials, International (ASTM). Some commenters agreed with this requirement. Commenters were concerned about the complexity and cost of meeting CPSC and ASTM standards. Some commenters suggested we reference the full names of the CPSC and the ASTM to improve clarity.

Response: We agree with commenters that it may be difficult for programs to identify all equipment and materials that are covered by the CPSC and the ASTM. Our understanding is that most equipment and material used in early childhood programs is labeled as compliant with applicable standards. In order to reduce potential burden for programs, we struck what was paragraph (b)(2)(iii) and revised paragraph (b)(2) to specify that indoor and outdoor play equipment, feeding chairs, strollers, and cribs must meet the applicable ASTM or CPSC standards and other materials and equipment used in the care of enrolled children must also meet those standards as applicable. We also included the full names of these entities for better clarity.

Comment: Some commenters recommended we include more specificity in paragraph (b)(2)(i). Specifically, they suggested we include specific language from *Caring for Our Children* about ensuring all indoor and outdoor equipment and materials and play spaces are clean and safe and appropriately disinfected.

Response: We did not revise paragraph (b)(2)(i) to make it more specific. We expect programs to determine what they must do to provide safe and healthy environments and encourage them to consult *Caring for Our Children Basics* or other similar resources for additional guidance.

Comment: We received comments on paragraph (b)(4) that address safety training. Commenters requested more clarification, such as what topics programs must include in the initial training and how often they must offer this training. They also asked us to clarify what positions are included under "all staff." Other comments offered recommendations for additional specificity to the required staff training topics. For example, some commenters recommended additional specificity about safe sleep practices, and some commenters suggest we add cold weather safety.

Response: We agree that we were not clear enough about which staff needed safety training and whether it was necessary for all staff to be trained on all required topics. Therefore, we revised paragraph (b)(4) to clarify what safety training was required for staff with regular child contact in paragraph (b)(4)(i) and what safety training was necessary for staff without regular child contact in a new requirement at paragraph (b)(4)(ii). We have also clarified that the areas of training provided should be appropriate based on staff roles and ages of children they work with. Further, we did not specify in paragraph (b)(4) of this section what topics programs must include in the initial training and how often must they offer this training. We expect programs to design training curricula and determine how often this training must be provided in order to ensure staff are properly trained to keep children safe. We did not make revisions to address other requests for more specificity because we did not think we did not believe that level of prescription was necessary to ensure child safety.

Comment: Commenters recommended we replace "spills of bodily fluids," with "exposure to blood and body fluids" in hygiene practices.

Response: We revised this requirement accordingly, now found at paragraph (b)(6)(iii).

Comment: We received many comments about safety requirements for addressing child food allergies, which we addressed primarily in what was paragraph (b)(8)(vi) in the NPRM and is paragraph (b)(7)(vi) in the final rule. Many commenters were concerned the requirement created privacy concerns and offered alternative suggestions. Some commenters were concerned standards were not strong enough and parents might decline to enroll their child. Specific recommendations included: Implementation of a system to share allergy information with relevant staff; to have a training system to ensure staff are prepared to manage allergy related emergencies; posting a list under a sign indicating that there is confidential information; and making sure all staff are aware of all allergies and using scan cards that include allergy information.

Response: A program's most critical responsibility is to keep children safe. We did not make changes to the food allergy requirements in paragraph (b)(7)(vi). We require programs to implement administrative safety procedures, including posting child allergy information prominently where staff can view where food is served. We do not believe this requirement creates privacy concerns. We believe that with the very young children that Head Start serves, the threat posed by any staff or volunteer who is serving food not knowing about a child's allergy is a far greater threat than others knowing about a child's food allergy. We have also made this clear in subpart C of part 1303 on Protections for the Privacy of Child Records.

Comment: We received comments about the requirement in paragraph (c) that programs must report any safety incidents in accordance with § 1302.102(d)(1)(ii). For example, commenters requested clarification about the timeline or suggested the reporting requirement was unnecessary. We received many comments about § 1302.102(d)(1)(ii) to which this requirement in paragraph (c) is aligned.

Response: We revised § 1302.102(d)(1)(ii) to reflect the many comments we received on that requirement. We discuss those comments and our revision in subpart J. We think those revisions provide sufficient clarity for this provision.

Family and Community Engagement Program Services; Subpart E

This subpart includes program requirements for family and community engagement services. It requires programs integrate family engagement into all systems and program services. It also includes the strategies and approaches programs must use for family engagement and strengthens the requirements for offering parent activities that promote child learning and development. Further, it details the family partnership process, including identification of family strengths and needs and individualized family partnership services. Finally, it details program requirements for community partnerships and coordination with other programs and systems. This subpart retains many provisions from the previous program standards but consolidates, clarifies, and reorganizes them and strengthens them with a greater focus on family services outcomes instead of processes and a requirement to offer research-based parenting curriculum.

We received many comments on this subpart. Some commenters supported the improved flexibility, attention to children's learning, and integration of family engagement. However, many commenters were concerned this subpart contributed to an overarching theme of a weakened role for parents. We believe parents are foundational to Head Start's success and that Head Start's two-generation approach is integral to its impact on the children and families it serves. It was not our intent to diminish the role of parents in the NPRM. The NPRM built on the groundbreaking work of the Parent, Family and Community Engagement Framework (PFCEF) to focus on system-wide parent, family, and community supports that would create a roadmap for progress in achieving the types of outcomes that lead to positive and enduring change for children and families. However, it was clear from public comments that we needed to revise provisions to ensure the integral role of parents in Head Start is appropriately reflected in the final rule. We discuss public comments as well as our responses and revisions below.

General Comments

Comment: Many commenters expressed concern that family partnership services were too focused on child development and learning and recommended we revise them to focus more broadly on strategies to enhance families' social and economic well-being and leadership skills. In addition to recommending revisions to separate parent and family services from child learning and development, some commenters offered specific suggestions, such as identification of economic well-being as part of family well-being and pilot programs to support two-generation practices.

Response: Section 636 of the Head Start Act specifies the purpose of Head Start is to improve the school readiness of children and provide services to families that support children's cognitive, social, and emotional development and school readiness. Research shows that family social and economic well-being greatly impacts children's development and school readiness,[101] [102] [103] [104] [105] which is why two-generation approaches like Head Start are so important. We revised § 1302.50(a) to further clarify the purpose of parent and family engagement as supporting children's learning and development. We made substantial revisions in §§ 1302.50 and 1302.52 to clarify that family partnership services should include the depth and breadth appropriate to support families. We also revised §§ 1302.50(b)(3) and 1302.52(a) to clarify that family well-being includes family safety, health, and economic stability. Thus, we believe the final rule appropriately reflects the statutory requirement that family engagement services be provided to improve children's learning and development and the importance of strong family partnership services in support of that purpose.

Comment: Many commenters broadly recommended revisions to emphasize the key role of parents in all areas of program operations.

Response: We agree that parents should be engaged in all aspects of program operations. Effective, comprehensive family engagement depends upon strategies that support family well-being and family engagement being embedded throughout systems and services. We believe the rule accomplishes this integration and note that collaboration with parents and families and parent and family engagement and services are integrated into all program services. In addition to the extensive parent and family services required in this subpart and in Program Governance, parent and family engagement services are integrated throughout program operations. For example, we integrate these services in the education subpart (*e.g.,* § 1302.34), the health services subpart (*e.g.,* §§ 1302.41 and 1302.46), the disabilities subpart (*e.g.,* § 1302.62), the transitions subpart (§§ 1302.70(c) and 1302.71(b)), personnel policies (*e.g.,* §§ 1302.90(a) and 1302.92(c)(3)), and program management (subpart J). However, we did make some revisions to address this concern. As previously noted, we reinstated parent committees as part of the governing structure in part 1301. Also as previously noted, we revised the family engagement section title in the Education and Child Development subpart to reflect the broader nature of parent and family engagement. In addition, to reflect that family and community program services in this subpart are not limited to partnership services, we revised the subpart title to read "Family and Community Engagement Program Services." We also revised § 1302.50(b)(1) to recognize parents as children's primary "teachers and nurturers" to more specifically define the parent's role.

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Comment: Many commenters recommend we reorganize part 1302 to place subpart E—Family and Community Engagement Program Services—before subpart C—Education and Child Development Services. They stated this would help convey the centrality of parent engagement to Head Start.

Response: We agree that parent engagement is foundational to Head Start. We think this is appropriately reflected in this subpart as well as in parent-related provisions integrated into every other subpart in part 1302—Program Operations. Therefore, we do not think reorganizing the subparts is necessary to reflect parents' essential roles in the lives of their children and as partners in the Head Start program. We did not reorder any subparts in part 1302.

Comment: Some commenters recommended we do more to integrate the Parent, Family, and Community Engagement Framework (PFCEF) into the rule. For example, some commenters recommended we include the PFCEF title and outcomes definitions into the rule. Others recommended we add more specificity related to the PFCEF and/or stronger requirements to track and measure progress in the outcomes included in the PFCEF.

Response: We agree programs have made important progress in service delivery through integration of the PFCEF in their systems and services. Therefore, this subpart included many of those key strategies and approaches, including a strong focus on family engagement outcomes. In response to comments, we revised the final rule to provide clearer identification of PFCEF outcomes in § 1302.52(b), alignment of the individualized family partnership services to the PFCEF outcomes in § 1302.52(c)(1), and stronger requirements for tracking outcomes in § 1302.52(c)(3).

Section 1302.50 Family Engagement

This section included the fundamental requirements that apply broadly to all parent and family engagement activities as well as general parent and family program practices. It requires programs to integrate family engagement strategies into all systems and program services and details fundamental requirements for approaches to family engagement. To address overarching concerns about conveying the centrality of family engagement and the important role of parents, we made some structural and other revisions to requirements in this section. In addition to some of the revisions to paragraph (a) that we previously noted, we made revisions such as changing the section title from "In general" to "Family engagement" and deleting the reference to community partnerships to clearly differentiate requirements in the sections related to family engagement in §§ 1302.50, 1302.51, and 1302.52 from the requirements for community engagement in § 1302.53. We also added the title "Family engagement approach" to paragraph (b) and changed the structure for the lead-in to paragraph (b) so that its requirements for family engagement are clearly delineated. We discuss comments and our responses below.

Comment: Some commenters suggested revising the requirement in what was paragraph (b)(2) in the NPRM and has been moved to paragraph (b)(6) in the final rule to ensure information is provided in a family's preferred language to ensure that they access and participate in services. Another commenter recommended we explicitly require materials be accessible to families who are "low literacy" or not proficient in English.

Response: Though we agree it is important that programs make information and services available in the languages spoken by enrolled families, we also understand that programs may have a dozen or more languages represented among their enrollment at any one time and that some languages may be spoken by only a few members of a community. We believe that our requirement in what is now paragraph (b)(6) is appropriately specific. We also have confidence that programs will consider the needs of the families they enroll, including literacy, in their interactions with families.

Comment: Some commenters supported the father engagement requirement in what was paragraph (b)(3) in the NPRM. Other commenters stated that father engagement should not be mandated. Some offered additional suggestions, such as adding the term "male" to father engagement to include the men who participate in raising children who are not their biological fathers and explicitly adding services for lesbian, gay, bisexual, and transgender (LGBT) parents.

Response: The definitions of "family" and "parent" under part 1305 allow for many variations of people who may have the role of parents or guardians or as authorized caregivers. We have retained a focus on "father engagement," which is in paragraph (b)(1) in the final rule, because research demonstrates that child outcomes improve when fathers are positively involved. This does not preclude the engagement of other males who may have significant roles in children's lives so we do not think we need a broader requirement. While the regulation requires that programs implement strategies to engage fathers in their children's learning and development, this is not the same as mandating father engagement for every father. In fact, the requirement in § 1302.15(f) explicitly states that parent participation is not required. Because of the inclusive definitions we provide for "parent" and "family," we did not amend the section to specifically list LGBT parents.

Comment: Some commenters recommended replacing the phrase "responsive to and reflect" with "incorporates" in paragraph (b)(2).

Response: We agree and made this revision.

Comment: Commenters believed the provisions in this section weakened family services, and requested changes to ensure that Head Start's two-generation approach to addressing family needs is not diminished. Some of these commenters requested that Head Start programs be allowed to utilize innovative two-generation approaches to deliver services to families of enrolled children.

Response: As stated previously, it was not the intent of the NPRM to diminish or weaken the critical role that Head Start programs play in supporting families of enrolled children. In addition, Head Start programs have always been allowed to utilize two-generation approaches to deliver services to families of enrolled children, and many already do. However, we added a provision in paragraph (b)(4) to clarify that programs should implement innovative strategies to address prevalent needs of families across the program. This provision further acknowledges that in order to implement such strategies effectively, programs may need to leverage community partnerships or other funding sources.

Section 1302.51 Parent Activities To Promote Child Learning and Development

This section includes requirements for activities programs must provide to parents to assist them in promoting child development and learning. It included a new requirement that programs offer the opportunity for parents to participate in research-based parenting curriculum. We revised this section to include the requirement for working with parents to support regular child attendance from § 1302.50(b)(1) in the NPRM. We believe it is more appropriately placed in this section. We also addressed the concern that we did not adequately reflect the important role of parents in children's learning with revisions in the introductory text in paragraph (a) and paragraph (a)(1).

Comment: As previously noted, some commenters recommended we combine the requirements of this section with the requirements of § 1302.34. Others recommended a reorganization to amplify the importance of supporting children's learning as a purpose for family engagement.

Response: We did not make this revision. We believe § 1302.34 appropriately integrates parent and family engagement into center-based and family child care education services that are focused on the child. The activities in this section are parent-focused. We think this organization better conveys the importance of integrated family engagement services throughout program operations and reflects which staff will primarily engage in the service delivery.

Comment: Some commenters suggested adding language to the regulation on informing parents about the importance of bilingualism.

Response: We agree that programs should provide parents with information about brain development, including bilingualism. We added paragraph (a)(3) to reflect this suggestion.

Comment: Some commenters supported the requirement in paragraph (b) for a research-based parenting curriculum, noting it would raise program quality. Some requested further clarification, such as a list of acceptable curricula or whether adaptations could be made to the curricula. Others recommended we add more strengths-based language to the requirement. Some commenters opposed this requirement for reasons such as cost and concern appropriate research-based curricula were unavailable or suggested participation be optional because it would be burdensome to working parents.

Response: We think this requirement will improve the quality of service delivery. We do not think further clarification is necessary, but agree that the requirement should be strengths-based and revised paragraph (b) to reflect that characteristic. We also clarified that significant adaptations could be made to better meet the needs of the populations served, but that in such cases programs must work with an expert to develop these adaptations. Technical assistance is available on available research-based parenting curricula through the Early Childhood Learning and Knowledge Center. We note that parent participation is never required as criteria for a child's enrollment in Head Start.

Section 1302.52 Family Partnership Services

This section details the family engagement service requirements programs must provide to identify family needs and goals and provide services and supports to help meet family needs and achieve their goals. It requires a family partnership services approach that is initiated as early as possible, shaped by parent interest and need, focused on outcomes instead of process, and effectively targeted program and staff resources based on need to ensure appropriate levels of service intensity. We designed this section to align with the Parent, Family, and Community Engagement Framework that has helped programs develop an ongoing process of individualized services based on family strengths and needs instead of the development of a single written plan. Many commenters strongly opposed our elimination of a specific family partnership plan. Though we intended to strengthen family engagement services with requirements that detail an ongoing outcomes-focused process, commenters believed this section diminished family engagement services and contributed to an overall weaker role for parents in Head Start. We address these and other comments below.

Comment: Many commenters strongly suggested we restore the written family partnership agreement. Commenters articulated concern that removal of the requirement for a written agreement weakened family services in Head Start. Other commenters thought that eliminating the requirement for a written agreement meant we eliminated the family goal setting process. Though some commenters agreed that the paper document can become more of a paperwork process than the means to supporting families in identifying and achieving goals, they still felt that the written agreement is an important step in formalizing the process. Some commenters expressed support for the increased local flexibility afforded by not requiring a written agreement.

Response: We intended for this subpart and this section specifically to streamline requirements, place an emphasis on outcomes over process, and allow more local flexibility to implement effective processes and strategies for meeting family service outcomes. We did not intend for this section to diminish the program's two-generation approach or the strength and breadth of family services.

We made revisions to this subpart and section to clarify our intent for the family partnership services, including that it must include a family partnership agreement. We added this provision in § 1302.50(b)(3). We also added § 1302.50(b)(5) in the final rule to require a program's family engagement approach to include partnership with families to identify needs, interests, strengths, goals, services and resources that support parents. As previously noted, we revised paragraph (a) in this section to clarify that family well-being includes family safety, health, and economic stability. Also as previously noted, we revised paragraph (b) to strengthen alignment between intake and family assessment procedures and identification of family strengths and needs to the outcomes of the Parent, Family, and Community, Engagement Framework. These changes help clarify that the rule does not narrow the breadth or depth of family services that are ultimately aimed at promoting the school readiness of children.

Finally, we made significant revisions to paragraph (c) to detail the full process of family partnership services. In paragraph (c)(1), we require programs to offer individualized services that identify family interests, needs, and aspirations related to the family engagement outcomes in the PFCEF. In paragraph (c)(2), we require programs to help families achieve their identified outcomes. In paragraph (c)(3), we require programs to establish and implement a family partnership agreement process, including a family partnership agreement, to review family progress, revise goals, evaluate and track whether identified needs and goals are met, and adjust strategies on an ongoing basis. In paragraph (c)(4), we provide programs with flexibility to target resources to ensure appropriate levels of service intensity.

We believe the revisions to this section and to § 1302.50 strengthen program quality through a focus on outcomes instead of process, dispel concerns about the rule diminishing family partnership services, and will ensure programs implement strong and effective family partnership services that strengthen families and improve child outcomes.

Comment: Some commenters suggested we clarify whether parent goals should focus on the parent or the parent's goals for the child. Others recommended that we be more explicit about data and performance indicators related to family services and well-being.

Response: We believe this subpart provides appropriate flexibility for parents to identify their needs, goals, and aspirations so we did not include additional specificity about the types of goals parents set. We revised this section to reframe a requirement that was in paragraph (c)(2) in the NPRM and paragraph (c)(3) in the final rule to ensure programs review, evaluate, and track family needs and goals and appropriate strategies on an ongoing basis.

Section 1302.53 Community Partnerships and Coordination With Other Early Childhood and Education Programs

This section includes program requirements for community partnerships. It largely maintains provisions from the previous performance standards about ongoing collaborative relationships and partnerships with community organizations. It requires programs take an active role in promoting coordinated systems of comprehensive early childhood services. It added a new requirement for a memorandum of understanding with the appropriate local entity responsible for managing publicly funded preschool programs to reflect requirements from the Head Start Act. It also added new requirements for coordination with state and local Quality Rating and Improvement Systems and state data systems to ensure that we are maximizing access to services, reducing duplication and fostering informed quality improvement.

We reorganized and retitled this section to improve clarity. For example, we reorganized §§ 1302.50 and 1302.54 so community partnership requirements were solely consolidated under § 1302.53. We reorganized this section to describe program requirements for ongoing collaborative relationships and partnerships with community organizations in paragraph (a). We moved what was paragraph (a) in the NPRM to paragraph (b) in the final rule and restructured requirements for memorandum of understanding, QRIS, and data systems to fall under paragraph (b) to better articulate the linkages between these three requirements and those in paragraph (b) that require programs take an active role in promoting coordinated systems of comprehensive early childhood services. We also revised and moved the requirement to participate in statewide longitudinal data systems from subpart J to this section.

We also moved the requirement about Health Services Advisory Committees from paragraph (c) to § 1302.40(b). In addition, we renamed this entire section "Community partnerships and coordination with other programs and systems" to more clearly identify its applicability and purpose. We received many comments on this section. We discuss them and our responses below.

Comment: We received many comments on the community partnership requirements described in what is now paragraph (a) but was paragraph (b) in the NPRM. Many commenters suggested we add new partners with which programs should establish collaborative relationships and partnerships, such as programs funded through the Runaway Homeless Youth Act, financial partners, and school boards. Other commenters were concerned we removed explicit mention of nutrition and housing assistance agencies. Some commenters recommended we not add any specific community partnerships and let programs decide based on community data. Some commenters requested additional clarification, such as for greater specificity for coordinating community plans or whether we will allocate funds to comply with this section of the regulation.

Response: We agree that there are a variety of potential partners with the capacity to help meet the comprehensive needs of children and families. However, rather than continue to add to the list of potential specific partnerships, we believe programs will appropriately assess their family and community needs and identify partnerships that will support their service delivery. In addition, we note this section promotes local flexibility in the development of community partnerships and there is no requirement for a program to have community plan. Programs may request additional assistance for guidance with the development of community plans and partnerships. Finally, Congress appropriates funds for the Head Start program. We do not have the authority to provide additional funds.

Comment: We received many comments about our proposal, now found in paragraph (b)(2), that stated programs should participate in their state or local QRIS under certain conditions. Some commenters supported this requirement for reasons including: it increases a program's marketability; it improves information available to parents; it can reduce inefficiencies and inequities by aligning Head Start programs with other child care and state pre-kindergarten programs; it encourages quality improvement; it could direct more families to Head Start; and it makes progress toward common indicators of quality across programs. Some commenters asked for clarification, such as how to incentivize participation in QRIS. Other commenters suggested revisions, such as moving it to another section or adding criteria for specific subgroups such as DLLs.

Many commenters opposed this requirement and recommended its removal. Commenters expressed a number of reasons including: QRIS is not available in every state; it is duplicative of monitoring, licensing, and NAEYC accreditation; it would be too costly and burdensome; and research is mixed on its benefits to programs or families.

Response: We believe it is important that Head Start programs participate in state or local quality improvement efforts and that the value of QRIS outweighs the challenges, including giving parents more informed choices about the quality of programs. While it is true that most local education agencies are exempt from licensing, Preschool Development Grants require participation in QRIS. We believe this signals recognition of the value of QRIS participation and that as participation occurs across the spectrum of programs; it will continue to strengthen both local programs and the QRIS itself. We also recognize that there may be challenges that make it difficult for all programs to participate in QRIS, including wait times, and a lack of validated systems. However, we also understand that unqualified mandated participation could lead to duplication in monitoring and rating and that the conditions as we outlined them in the NPRM may have been too stringent. Therefore, we modified this provision in the final rule. Specifically we removed the qualifier that the tiers must be validated and added a condition that the state must accept Head Start monitoring data as evidence of meeting indicators in the

QRIS tiers and that participation must not impact a program's ability to meet Head Start standards. We believe the final rule sets a strong and reasonable way for Head Start programs to participate in these important state systems without duplication and burden.

Comment: Some commenters opposed the requirement for tribal programs specifically, stating that it was not appropriate in these service areas.

Response: We agree that state and local QRIS systems are not comparably structured to serve in tribal areas as they are in other service areas. Therefore, we revised paragraph (b) to clarify that tribal programs only need to consider whether participation in state or local QRIS would benefit their programs and families.

Comment: Some commenters requested we combine the two standards on Statewide Longitudinal Data System (SLDS): one in this section and another in § 1302.101 on partnering with the SLDS, and requested clarification of the requirements.

Response: We agree with this comment and think that the two mostly duplicative requirements may lead to confusion. Thus, we removed the requirement from § 1302.101 and combined it into § 1302.53. In the process, we dropped the terms "early childhood data systems," "statewide data system," and "Statewide Longitudinal Data System" and replaced them with "state education data systems" to make it non-program specific and less confusing.

Additional Services for Children With Disabilities; Subpart F

This subpart includes the standards for additional services for children with disabilities and their families. These provisions align with the Act and reflect requirements that children must be identified and receive services as prescribed in IDEA, focus on effective service delivery instead of outdated or unused documentation, and incorporate best practices. In order to communicate its critical importance, we also incorporated requirements for the full inclusion and participation of children with disabilities in all program activities, including but not limited to children eligible for services under IDEA. Commenters generally supported our overall approach to serve children with disabilities and their families. We discuss these and additional comments below.

General Comments

Comment: Some commenters were concerned our elimination of what was part 1308 in the prior rule meant we eliminated requirements for services to children with disabilities.

Response: While there is no longer a part 1308, the final rule preserves the critical role of Early Head Start and Head Start programs in screening and referring children with suspected disabilities and as a program where children with disabilities are prioritized for services and fully integrated into every aspect of service delivery. We believe the final rule builds upon Head Start's long-standing commitment to serving children with disabilities and strengthens these services through part 1302. The final rule reflects the appropriate role of local agencies responsible for implementing IDEA, as required by IDEA, for evaluation, eligibility for services, establishment of an IFSP or IEP, and implementation of early intervention services or special education and related services, as appropriate.

Comment: Some commenters suggested we include additional services or specific approaches to service delivery in this subpart. For example, some commenters suggested audiology services or Applied Behavioral Analysis be added under this subpart.

Response: It is not our role to identify the specific type of special education and related services used with children with disabilities. We think audiology screening for all children is essential and require it under subpart D, which addresses health services. We did not make revisions.

Comment: Commenters suggested adding a requirement to ensure DLLs struggling with English acquisition are not misidentified as having a developmental delay or disability. Some commenters suggested that staff should receive training to work with DLLs who also have disabilities.

Response: We believe these topics are more appropriate for technical assistance or guidance.

Section 1302.60 Full Participation in Program Services and Activities

This section includes an outline of the requirements contained in this subpart and an assurance that all children with disabilities, including but not limited to those who are eligible for services under IDEA, receive all applicable program services and are able to fully participate in all program activities.

Comment: Many commenters recommended we revise this section to include specific reference to inclusive program practices.

Response: We agree that it is essential to specify that services should be provided in the least restrictive possible setting and made revisions to reflect this clarification.

Section 1302.61 Additional Services for Children

This section describes the additional services programs must provide to children with disabilities and children referred for but awaiting the determination of IDEA eligibility by the local agency responsible for implementing IDEA. It requires programs meet the individualized needs of children with disabilities and provide any necessary modifications and supports necessary to support the full participation of children with disabilities. It includes a new requirement for programs to provide individualized services and supports to the maximum extent possible to children awaiting determination of IDEA eligibility. Further, it includes additional services for children with an IFSP or IEP. Commenters were generally supportive of this section but raised some concerns and suggestions, which we discuss below.

Comment: Some commenters offered unqualified support for this section, but others expressed concerns about the proposal in paragraph (b) to provide services and supports while children are awaiting determination of IDEA eligibility. For example, concerns included program staff may not have the expertise to know what services should be provided, the cost of services. Some commenters stated the standard was unnecessary because programs already individualize services for children.

Response: There is sometimes a significant delay in local agencies determining eligibility for IDEA and the development of an IFSP or IEP; even though both IDEA Part C and Part B have timelines for conducting evaluations, and for developing an IFSP or IEP once the eligibility determination has been made. Therefore, we think it is important that programs review all reasonable avenues for providing services that maximally support a child's individual needs, including services and supports for which the child may be eligible through insurance pending an eligibility determination under IDEA and the development of an IFSP or IEP. However, we made revisions to paragraph (b) to clarify our expectations including that programs should work with parents to determine if services and supports are available through a child's health insurance and/ or whether they should be provided pursuant to Section 504 of the Rehabilitation Act if the child satisfies the definition of disability in section

705(9)(b) of the Rehabilitation Act. When such supports are not available through alternate means while the evaluation results are pending, though staff are not required to provide early intervention services or special education and related services, programs must individualize program services based on available information such as parent input and child observation, screening, and assessment data. We also clarify in paragraph (b) that program funds may be used for this purpose.

Comment: Some commenters stated they would like to be able to include children who receive services while IDEA eligibility is pending, as described in paragraph (b), in the calculation to meet the requirement that ten percent of total enrollment are children with disabilities.

Response: Though we understand that not all children with disabilities are eligible for services under IDEA, the Act stipulates that children must have an IFSP or IEP under IDEA to be counted as a child with a disability. Therefore, we have no authority to change how the ten percent requirement is calculated. We did not revise this provision.

Comment: Some commenters suggested we require the local educational agency to operate and coordinate with the Head Start program, similar to how Head Start is required to form agreements with the local educational agency.

Response: We appreciate that this would foster collaboration but we have no authority over local educational agencies. Programs are encouraged to develop ongoing working relationships with local agencies responsible for implementing IDEA.

Comment: Some commenters offered suggestions to further strengthen and clarify the standards for additional services for children with an IFSP or IEP.

Response: In response to these comments, we revised paragraph (c)(1)(iii) and added a new standard at paragraph (c)(1)(v). The revision to paragraph (c)(1)(iii) clarifies that many elements of an IFSP or IEP will be implemented by "other appropriate agencies, related service providers and specialists." Our addition at paragraph (c)(1)(v) clarifies that most services can be effectively delivered within the classroom setting. Providing services in the "natural environment" reduces transitions, increases inclusion, and increases the opportunity for gains to be generalized. We think it is an important stipulation that programs should work with parents and agencies responsible for implementing IDEA so that IFSPs and IEPs specify that services be delivered within children's own classes or family child care homes, if determined appropriate for the child.

Section 1302.62 Additional Services for Parents

This section described the additional services programs must implement to support the parents of children with disabilities. These standards reorganize, clarify, and build upon previous regulations.

Comment: A commenter recommended that programs be required to provide information to their state parent and health assistance centers. Another commenter recommended we clarify some of the difference between Parts B and C of IDEA.

Response: Though we agree this can be useful information, it is not universally applicable and can be effectively provided as guidance or technical assistance so we did not make revisions. We believe our definition of "local agency responsible for implementing IDEA" is sufficiently clear and did not add further clarification.

Section 1302.63 Coordination and Collaboration With the Local Agency Responsible for Implementing IDEA

This section describes program requirements to coordinate and collaborate with the local agency (or agencies) responsible for implementing IDEA. This section retains many provisions from the previous regulation but streamlines and updates them to focus less on planning and more on service delivery. We believe coordination and collaboration with the local agencies responsible for implementing IDEA reflect an essential partnership in meeting the needs of children with disabilities in Head Start. Commenters generally supported this section.

Comment: Commenters expressed concern that children with disabilities sometimes are required to leave Early Head Start or Head Start or be dually enrolled to receive special education and related services at another site and offered recommendations to strengthen our standards.

Response: We fully support the requirements of IDEA that services must be provided in the least restrictive possible environment. We revised paragraph (b) to address concerns about dually enrolled children and the setting in which children receive services.

Transition Services; Subpart G

This subpart describes requirements for supporting transitions for children and families as they move between programs and settings. This subpart reorganizes and updates previous standards to reflect best practice for better clarity and implementation. Commenters supported many of the provisions in subpart G, such as the detailed requirements for activities to support transitions into kindergarten or other early childhood programs, the requirements for transitions of children with IEPs or IFSPs, the language focused on supporting transitions for children in migrant and seasonal Head Start programs, and the removal of the requirement to have a staff-parent meeting at the end of the year. We received other comments on this subpart and respond to them below.

General Comments

Comment: Some commenters suggested that implementing the additional supports for transitions between Early Head Start to Head Start and from Head Start to kindergarten will impact programmatic procedures and budgets, and that additional funding will be needed. Others were concerned this subpart placed too much burden on the program from which a child is exiting and suggested revisions.

Response: We believe the transition services in this subpart are critical to support child development from birth to age five and beyond. This rule supports the transition process and continuity of services regardless of where families seek services, but we do not believe they are substantially different than current practice. However, we agree that programs cannot control the receiving school or program, but our language supporting transitions and collaborating with community partners is sufficiently flexible to allow for these realities. Therefore, we did not revise the provisions.

Comment: Some commenters recommended that we include requirements for programs to assess their transition practices to ensure they effectively minimize the number of transitions and promote smooth transitions for children and families.

Response: Although we encourage programs to assess all aspects of their programming as part of the continuous quality improvement process, we do not agree that requiring programs to specifically assess their transitions practices is necessary.

Section 1302.70 Transitions From Early Head Start

This section describes what programs are required to do to support successful transitions for children leaving Early Head Start. The requirements in this section also support parents' continued involvement in their child's education.

Comment: Commenters expressed concern about the requirement in paragraph (b)(2) on the timing of moving children from Early Head Start to Head Start after their third birthday. Some commenters recommended we allow a child who turns three after the kindergarten cut-off date to remain enrolled in Early Head Start until the child transitions into Head Start or to another program at the beginning of the next program year. Also, some commenters recommended we clarify the phrase "a limited number of additional months" in paragraph (b)(2) because this timeframe is vague.

Response: The Act sets the age requirements for Early Head Start. We encourage programs to use ongoing planning processes to make informed choices based on individual needs and development for appropriate enrollment options into Head Start, pre-kindergarten, or other community based programs, to the extent available in their communities. Additionally, we used the phrase "a limited number of additional months" to provide programs with flexibility to determine the appropriate number of months to extend a child's enrollment to ensure a smooth transition. Children that turn three after the date of eligibility for kindergarten can enroll in Head Start if there is a space available during the program year. Therefore, we did not revise the provision.

Comment: Some commenters supported the requirements in paragraph (d) for Early Head Start and Head Start to work together to support continuity of services from birth to five. Some commenters recommended specific revisions, including adding a requirement to paragraph (d) for programs to serve families with the highest demographic risk.

Response: Prioritization requirements are described in subpart A, so we have not made changes to this section.

Section 1302.71 Transitions From Head Start to Kindergarten

In this section, we outline the services programs must implement to support successful transitions from Head Start to kindergarten. We received comments from the public and address them below.

Comment: One commenter suggested we change the phrase "transition to kindergarten" to "transition to school" throughout this section to better emphasize that broader transitions may occur between Head Start and the public school system, such as state preschool.

Response: This section focused on supports for transitions to kindergarten, while § 1302.72 already addressed transitions to other early childhood education programs.

Comment: One commenter expressed concern that the language in paragraph (b)(2)(iii) on transition services to prepare parents to exercise their rights and responsibilities including options for their child to participate in language instruction educational programs, does not reflect the intent of Section 1112 of the Elementary and Secondary Education Act (ESEA), as referenced in the Act, and that programs should tell parents about the range of educational options available to DLLs when they enter elementary school. This commenter suggested that we should not promote native language instruction over other options. Additionally, other commenters requested clarification about whether Head Start programs are required to judge the appropriateness of different instructional approaches for DLLs in public schools.

Response: As described in section 642A of the Act, Head Start programs are required to help parents of DLL children understand the information provided to them under Section 1112 of ESEA. We believe that paragraph (b)(2)(iii) is consistent with this requirement; however, for clarity, we removed the explicit mention of "native language instruction." Further, Head Start programs are not expected to judge the appropriateness of different instructional approaches for DLLs; rather, programs should help make parents aware of different options for language instruction programs in the elementary school setting. We made appropriate edits to paragraph (b)(2)(iii) to clarify this intent.

Comment: Some commenters stated that requirements in this section were too challenging and burdensome. For example, some commenters expressed concern that collaboration with school districts receiving Head Start children is challenging and highlighted collaboration to determine the availability of summer school programming for children entering kindergarten as an example.

Response: We believe that supporting successful transitions of children and families into school is critical for supporting child development and continued parental involvement in children's education. We do not agree that this section is too burdensome or challenging so we did not make changes in response to these comments.

Comment: Some commenters suggested we include additional requirements in this section to make transition services stronger. For example, commenters recommended we expand transition services to encompass after care in kindergarten and suggested we include more requirements on community collaborations in this subpart.

Response: We think we focus on the key components of transition services to support families when children transition to kindergarten. As always, we encourage programs to identify the individual needs of Head Start children and families and work to meet those needs. Additionally, we believe that community collaborations are sufficiently addressed in § 1302.53(a), which requires programs take an active role in promoting a coordinated system of comprehensive early childhood services among community agencies and partners, so additional requirements about community collaboration were unnecessary.

Comment: One commenter recommended we permit programs to continue to provide comprehensive services to a subset of very at-risk families after those children transition to elementary school.

Response: Head Start is not authorized or funded to serve children and families after they leave Head Start.

Section 1302.72 Transitions Between Programs

In this section, we included three new provisions that will support transitions for children and families who might not otherwise receive such services.

Comment: Some commenters explicitly supported the provision for programs to make significant efforts to support transitions for children experiencing homelessness or in foster care when they move out of the community. Because of their high mobility rate, one commenter suggested that programs should anticipate transitions for these children, and that the language in paragraph (a) should include support for transitions to other early childhood programs, not just Head Start, as well as connections to other types of community services that can support these children.

Response: We agree with the suggestion to support transitions to other early childhood programs if Early Head Start or Head Start services are not available. We edited paragraph (a) to reflect this.

Comment: Some commenters expressed concerns about the requirement in paragraph (b) to provide transition services to families who decide to enroll their children in other high-quality early education programs in the year prior to kindergarten.

Challenges described include difficulty identifying participation in other programs by children who do not return to Head Start and lack of mandates on other public programs. Commenters asked for clearer definitions of the terms ‘‘high quality’’ and ‘‘practical and appropriate,’’ as well as guidance on determining the quality of other programs. One commenter stated that this transition strategy does not promote the continuity of care emphasized in the NPRM.

Response: We agree the term ‘‘high quality’’ is vague and difficult to determine during a transition process; therefore, we struck the term from this provision. The intent of this provision is to support the transition process, regardless of where families seek services. To allow for program flexibility, we retained the phrase ‘‘as practical and appropriate.’’ We will continue to provide guidance on these terms, as requested by grantees.

Services to Enrolled Pregnant Women; Subpart H

This subpart describes services Early Head Start programs must provide to pregnant women enrolled in their programs. Long standing research clearly demonstrates the importance of prenatal care and the effectiveness of prenatal interventions to facilitate healthy pregnancies [106] [107] [108] [109] [110] and improve child outcomes that affect later school readiness [111] [112] [113] [114] [115] among at-risk women. While most of this subpart is structurally different from § 1304.40 in the previous rule, it expands upon services we have always required to codify best practices and also highlights the importance of prenatal health care and education. Commenters generally supported this subpart. We discuss specific comments and our responses below.

General Comments

Comment: Commenters supported our overall approach that creates a standalone subpart for services to pregnant women as well as individual new requirements for services to pregnant women. Some commenters opposed the additional requirements we proposed for pregnant women while other commenters suggested programs would require additional funds if they increased services to pregnant women.

Response: We understand the concerns some commenters described, especially related to cost. However, pregnant women are enrolled in Early Head Start programs, and therefore, funding is provided for these services. This subpart primarily reflects current practice that was not included in the regulation. We retained this section to codify practices related to pregnant women.

Comment: Some commenters recommended programs carefully consider when to enroll pregnant women so that their children will be able to enroll in the Early Head Start program.

Response: While we agree with this comment, we do not think there is a need for a program performance standard to require such consideration.

Comment: Some commenters suggested that the entire subpart should refer to expectant families rather than pregnant women, or requested clarification about the scope of services required for a pregnant mother of an enrolled child who is not herself enrolled in Early Head Start.

Response: This subpart pertains only to enrolled pregnant women, and we revised § 1302.80(a) to further clarify this. While we made it clear that relevant services should include the entire expectant family, wherever possible, pregnant women are the family member who is enrolled in Early Head Start. Further, § 1302.46 describes services for expectant families of enrolled children that may be relevant, but programs must only provide opportunities to learn about healthy pregnancy and post-partum care to expectant parents of enrolled children who are not themselves enrolled. We did not make revisions based on these comments.

Section 1302.80 Enrolled Pregnant Women

This section describes the services programs must provide to enrolled pregnant women. It requires programs to assess whether or not enrolled pregnant women have access to an ongoing source of health care and health insurance, and if not, to facilitate their access to such care and insurance. It also includes a requirement for a newborn visit. We received comments on this section and discuss them below.

Comment: One commenter explicitly opposed the new requirement in paragraph (b) to assist pregnant women in accessing health insurance.

Response: Ensuring pregnant women have health insurance is critical to ensuring they receive adequate prenatal care. [116] [117] [118] We did not revise the provision.

Comment: Some commenters requested clarity about what we meant by ‘‘as quickly as possible’’ in regard to the requirement in paragraph (b) that programs support access to health care for pregnant women. Commenters suggested 30 or 45 days.

Response: While we agree that 30 or 45 days are both reasonable interpretations of ‘‘as quickly as possible,’’ in some cases this requirement should be met more quickly, and in other cases challenges may arise that prevent programs from providing these services within those timeframes. Therefore, it is not appropriate to regulate a precise time frame. We did not revise the provision.

Comment: Some commenters recommended we require programs to refer families to emergency shelters or transitional housing in cases of domestic violence or homelessness.

Response: Paragraph (c) already requires programs to refer families to emergency shelters or transitional housing, as appropriate.

Comment: Many commenters suggested we revise what was § 1302.82(b) to require programs to offer but not necessarily provide a newborn home visit within two weeks because families should have the right to refuse. Some commenters asked that programs be allowed to consider cultural practices and length of hospital stays or illness in requiring an initial home visit at two weeks.

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[112] Olds, D.L., Henderson, Jr., C.R., & Kitzman, H. (1994). Does Prenatal and Infancy Nurse Home Visitation have Enduring Effects on Qualities of Parental Caregiving and Child Health at 25 to 50 Months of Life? *Pediatrics, 93(1),* 89–98.

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[115] Reichman, N. E. (2005). Low birth weight and school readiness. *The Future of Children, 15*(1), 91–116.

[116] Marquis, M. & Long, S. (2002). The role of public insurance and the public delivery system in improving birth outcomes for low-income pregnant women. *Medical Care (40),* 1048–1059.

[117] Howell, E. (2001). The Impact of the Medicaid expansions for pregnant women: A synthesis of the evidence. *Medical Care Research Review,(58)* 3–30.

[118] Phillippi, J. C. (2009). Women's perceptions of access to prenatal care in the United States: A literature review. *Journal of Midwifery & Women's Health, 54*(3), 219–225.

Response: The initial home visit is planned with the pregnant woman and her family as part of prenatal services that a program provides and the timing of the visit can reflect the beliefs and circumstances of the family. We clarified this intent by revising what is now § 1302.80(d) to require that programs must schedule a home visit within two weeks.

Comment: Commenters requested clarification about the qualifications for the "health staff" mentioned in what was § 1302.82(b) who perform the two-week postpartum visit.

Response: We removed the reference to "health staff" in what is now § 1302.80(d) to clarify programs have flexibility to staff the home visit in a manner that is appropriate for individual family needs. We now call this visit a newborn visit.

Section 1302.81 Prenatal and Postpartum Information, Education, and Services

This section strengthens program performance standards pertaining to enrolled pregnant women by requiring programs to ensure all enrolled pregnant women have opportunities to learn about various relevant topics. It also makes clear that programs must address needs for appropriate supports for emotional well-being, nurturing and responsive caregiving, and father engagement during pregnancy and early childhood.

Comment: Some commenters suggested we revise paragraph (a) and the title of this section to clarify the expectation for the level of service delivery.

Response: For clarification, we have changed the title of this section and the phrase in paragraph (a) to "prenatal and postpartum information, education, and services."

Comment: Some commenters suggested that maternal and paternal depression should be included in the list of prenatal and postpartum services described in paragraph (a). Some commenters explicitly suggested that expectant families be screened for both prenatal and postnatal depression.

Response: We revised the language in paragraph (a) to include parental depression.

Comment: Commenters recommended we require programs to use tools and resources to assess risk factors and needs of expectant families. Further, some commenters requested inclusion of explicit requirements regarding the hours and days or number of home visits required for pregnant women.

Response: We believe we struck the right balance in allowing programs to determine the specific ways to achieve the outcomes and do not think additional prescriptive federal requirements are necessary. We did not make these changes.

Comment: Some commenters suggested additions to the required educational services regarding oral health for both pregnant women and newborns during the newborn home visit.

Response: We do not believe that discussing later oral health is an appropriate focus of this newborn home visit. We did not revise the provision.

Comment: Some commenters requested guidance about the availability of prenatal educational materials. Other commenters suggested that we issue guidance to make programs aware of the educational materials available free of charge through the CACFP regarding nutrition, physical activity, and breastfeeding.

Response: As commenters noted, there are materials available through USDA, and other sources that could be used, free of charge to provide prenatal educational services to pregnant women and their families. We believe programs can easily access this information and do not think changes are needed to the regulation.

Section 1302.82 Family Partnership Services for Enrolled Pregnant Women

This section describes requirements for programs to provide family partnership services for enrolled pregnant women.

Comment: Some commenters wanted this section to include specific language for including fathers and father engagement in family partnership services for enrolled pregnant women.

Response: We agree that the language should more explicitly reflect the role of fathers and revised paragraphs (a) and (b) accordingly.

Human Resources Management; Subpart I

In this subpart, we combined all previous performance standards related to human resources management into one coherent section. This subpart includes requirements for personnel policies, staff qualifications, training and professional development, and staff health and wellness and volunteers. We renamed the subpart Human Resources Management to better encompass the requirements in this subpart. We received many comments on this subpart. We summarize and respond to these comments below.

Section 1302.90 Personnel Policies

This section requires programs to establish written personnel policies and procedures, sets forth a background check process, standards of conduct for staff, consultants, and volunteers, and staffing requirements when programs serve DLLs. We received many comments on our background check requirements. We discuss these and other comments on this section below.

Comment: Commenters supported the general requirement in paragraph (a) that programs develop written personnel policies and procedures. Many commenters asked us to provide more clarity about the policy council's role in hiring and firing staff. Some commenters asked us to require programs to make policies and procedures available to all staff. Some commenters asked us to prescribe exactly what program policies and procedures must contain.

Response: We revised paragraph (a) to read, "A program must establish written personnel policies and procedures that are approved by the governing body and policy council or policy committee and that are available to all staff." We purposely devised this rule to be less prescriptive to afford programs flexibility and autonomy so we did not include additional specificity about personnel policies and procedures other than what is required in paragraphs (b), (c), and (d) in this section. We revised this paragraph to clarify that staff have access to the personnel policies and procedures and to reflect the Act's requirement that the governing body and policy council or policy committee must review and approve the program's personnel policies and procedures. We relied on the Act for the governance requirements on hiring and firing so we did not make any changes.

Comment: Commenters generally supported our background check requirements in paragraph (b), noting that they were in the best interests of children and align with the Head Start Act and Child Care Development Block Grant Act of 2014 (CCDBG). Commenters expressed some concern with potential costs associated with the requirements. Some commenters recommended additional alignment, such as with provisions from Section 658(H) of CCDBG that require programs to complete the background check process within 45 days. Some commenters asked us to mirror exactly what the Act states about background checks to minimize conflict. They did not interpret the Act to require fingerprints with criminal history records checks. Others requested additional amendments such as limits to fees a program may charge to process criminal history checks, mandates for confidentiality, an appeal process, and an exemption for some employees. Some commenters recommended we rename paragraph (b) to improve clarity.

Response: We believe our background check requirements align with the Act and generally align with section 658(H) of CCDBG. However, we did not change the timeframe we prescribed for programs to complete background checks. We believe 90 days is appropriate, particularly since the Act requires Head Start programs to complete one of the checks before hire. We did not address background check fees in this rule. We understand programs may bear costs associated with background checks and we encourage programs to use the resources available to them and consider ways to allocate funds differently to cover these costs. We do not think it is the best interest of Head Start children to allow exemptions from the background checks. In regard to concerns about privacy, we expect programs will address confidentiality in their written policies and procedures because paragraph (c)(1)(iv) requires programs to ensure all staff, consultants, and volunteers comply with confidentiality policies. We did not require programs to establish a background checks appeal process. If either prospective or current employees decide to challenge background check findings, we encourage programs to direct them to the state, tribal, or federal agency that conducted the check. We agree the title of paragraph (b) was not clear enough and have renamed it "Background checks and selection procedures."

Comment: Some commenters expressed concern about the legality of asking prospective employees for their dates of birth. Other commenters were concerned if we did not reference Title VII of the Civil Rights Act of 1964, programs could use background checks to discriminate in hiring practices against protected individuals such as African Americans and Hispanics.

Response: Dates of birth are probably the most important factor needed to identify an individual and are necessary to conduct background checks. The Age Discrimination in Employment Act of 1967 does not prohibit an employer from asking for date of birth or age. In fact, the U.S. Equal Employment Opportunity Commission (EEOC) specifically ruled that an employer that asks for date of birth or age does not automatically violate that act. As a best practice, the EEOC urges employers to clearly disclose to applicants why they need birth dates.[119] Title VII of the Civil Rights Act of 1964 (Title VII) requires employers to screen individuals based on criminal history in a manner that does not significantly disadvantage protected individuals, such as Hispanics and African Americans. In § 1303.3 we include Title VII of the Civil Rights Act among the other federal laws Head Start programs need to comply with.

Comment: Some commenters found our structure for paragraph (b) to be confusing and asked us to clarify whether programs must complete the background check before a person was hired or within 90 days. Commenters offered suggestions, such as adding a provision that required programs to hire individuals who otherwise cleared one of the checks before they were hired or to limit their access to children until all background checks are cleared.

Response: We agree that our structure for paragraph (b) made it difficult to clearly understand what type of background check needed to be conducted before or after an individual is hired. We did not change the background check requirements but we revised paragraphs (b)(1) and (2) to improve clarity. Paragraph (b)(1) now clearly requires programs to obtain either state or tribal criminal history records with fingerprint checks *or* federal criminal history records with fingerprints before an individual is hired. Paragraph (b)(2)(i) now clearly requires programs have 90 days after an individual is hired to obtain whichever criminal history check listed in paragraph (b)(1) they could not obtain before hire. It also states in paragraph (b)(2)(ii) and (iii) that programs have 90 days after an employee is hired to complete background checks with child abuse and neglect registries, if available, and sex offender registries. To ensure child safety while the all of the background checks are being completed, we added paragraph (b)(3) to require programs ensure the new employee will not have unsupervised access to children until their full background check process is complete.

Comment: Some commenters were concerned we would find programs either non-compliant or deficient if there were no child abuse and neglect registries in their state. Some commenters suggested we should specify whether programs must use state or national sex offender registry and we should require programs to conduct searches on the National Crime Information Center.

Response: We require programs to obtain checks from the national sex offender registry and state child abuse and neglect and sex offender registries, if available. We think the regulation is strong on ensuring child safety and do not think it is necessary to require programs to check the National Crime Information Center.

Comment: Some commenters recommended we require programs to conduct background checks on volunteers, contractors, and family child care providers.

Response: We agree contractor and family child care providers are required to have background checks. To clarify our intent we added the phrase "directly or through contract" to paragraph (b)(1) and clarify that transportation staff and contractors are also subject to these requirements, consistent with the policy proposed in the NPRM. We also clarify that all staff, consultants, and contractors are subject to this requirement. We do not require background checks for volunteers because there is some evidence this stifles parent volunteering and engagement, which is fundamental to Head Start's two-generation approach. Additionally, as described in paragraph (c)(1)(v) and § 1302.94(b), programs must ensure children are never left alone with volunteers.

Comment: Many commenters were concerned about language in the preamble about programs providing justification for hiring individuals with arrests or convictions in relation to what was paragraph (b)(3) in the NPRM and is now paragraph (b)(4). Commenters noted this caused unnecessary bureaucracy and a few thought it contradicted the Act.

Response: Paragraph (b)(4) in this rule requires programs to review each employment application to assess relevancy. It does not conflict with the Act and does not require written justifications.

Comment: We received some comments about disqualification factors. Some commenters suggested we revise what is now paragraph (b)(4) to clarify that school-based grantees can use whichever state-imposed disqualification factors apply to them. Some commenters suggested we allow tribes to use tribal disqualification factors. Some commenters asked us to list specific pre-employment or disqualification factors.

Response: We revised paragraph (b)(4), which was paragraph (b)(3) in the

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[119] *See www.eeoc.gov/facts/age.html* for more facts about age discrimination.

NPRM, to clarify programs must use "applicable state or tribal Child Care Development Fund (CCDF) disqualification factors in any employment decisions." However, because pre-employment and disqualification factors vary by state and tribe, we did not list those factors here.

Comment: Most commenters supported the requirement in what was paragraph (b)(4) in the NPRM but is now paragraph (b)(5) to conduct complete background checks every five years. They believed what we proposed aligns with background checks across multiple early childhood programs and with typical hiring practices. Some commenters opposed this requirement because it would impose undue costs for programs. Many commenters suggested exemptions for programs that have a more stringent system in place. Some commenters offered other alternatives to the five-year requirement, like use of consumer reporting agencies because they are fast and more comprehensive, and background checks more frequently than every five years.

Response: We agree that our five-year requirement that now appears in paragraph (b)(5) in the NPRM aligns with other program requirements and with typical hiring practices. We understand there may be costs associated with background checks. However, we believe child safety is paramount. Therefore, we expect programs to use resources available to them and to allocate funds differently, if necessary, to cover these costs. We revised paragraph (b)(5) to exempt a program from the five-year requirement if the program can demonstrate it has a more stringent system in place that will ensure child safety.

Comment: Some commenters asked us to clarify the requirement in what was paragraph (b)(5) and is now paragraph (b)(6) about consideration of current and former program parents for employment vacancies. They requested we clarify that programs are not required to consider otherwise qualified parents for positions if they do not apply.

Response: We revised paragraph (b)(6) to clarify that parents should be considered only for jobs for which they apply.

Comment: Some commenters asked us to define: "background check," "before and individual is hired," "clearance by registries," employment application," and the term "hire" as distinct from the phrase "an offer of employment."

Response: We did not define these terms or phrases. Programs should consider their ordinary and customary meanings.

Comment: Commenters generally supported the standards of conduct described in paragraph (c). Some noted their support of the requirements in what is now paragraph (c)(1)(ii) that prohibit staff from using food or physical activity or outdoor time as a reward or punishment. Some commenters requested we add more specificity to the requirements in paragraph (c)(1)(ii). For example, some requested we expressly ban physical, mechanical, and chemical restraint, as well as seclusion. Some commenters stated that the terms "isolation," "sarcastic," "derogatory," and "humiliation" were subjective and asked us to define them. Some commenters recommended we delete the list of what staff must not do and include a standard by which staff should aspire to conduct themselves instead.

Response: We do not think our standards of conduct in paragraph (c)(1)(ii) require more specificity. We made small changes to this paragraph to improve clarity that did not change meaning. For example, the prohibition on public or private humiliation, that was found in paragraph (c)(1)(ii)(I) in the NPRM, was moved to paragraph (c)(1)(ii)(F). We agree it was appropriate to add a requirement to the standards of conduct that expressed the positive and supportive behavior all staff, consultants, and volunteers must exhibit. This standard can be found at paragraph (c)(1)(i) and standards describing prohibitions that were in paragraph (c)(1)(i) in the NPRM are now found at paragraph (c)(1)(ii).

We did not define "isolation," "sarcastic," "derogatory," and "humiliation" because we expect programs to consider these terms' ordinary and customary meanings. Furthermore, we did not amend paragraph (c) to use the terms physical, mechanical, and chemical restraint or seclusion. We believe our standards of conduct clearly convey prohibition on restraint. Furthermore, the requirement now found in paragraph (c)(1)(ii)(B) that expressly prohibits isolation as a form of discipline and the requirement in paragraph (c)(1)(v) that prohibits staff from leaving children alone or unsupervised at any time more clearly convey our prohibition on seclusion.

Comment: Some commenters suggested we reference staff, contractors, and volunteers in paragraph (c)(1)(iii) so programs understand who must adhere to standards of conduct.

Response: We agree that we must clarify standards of conduct described in paragraph (c)(1) apply to staff, consultants, contractors, and volunteers. We revised paragraph (c) accordingly.

Comment: Some commenters requested we reaffirm Head Start's policy that does not exclude same sex couples and add "sexual orientation" to what is now paragraph (c)(1)(iii)

Response: We agree, and we revised paragraph (c)(1)(iii) accordingly.

Comment: Commenters generally supported that personnel policies include appropriate penalties for staff that violate standards of conduct. Commenters asked us to clarify paragraph (c)(2), which requires personnel policies and procedures to include appropriate penalties for staff who violate the standards of conduct. Commenters requested to know who determines appropriate penalties.

Response: We expect programs to designate staff that will determine appropriate penalties. We think local programs are best suited to determine who that staff should be so we did revise the provision. We also clarified in paragraph (c)(2) that personnel policies and procedures must include appropriate penalties for consultants and volunteers, as well as staff, who violate the standards of conduct.

Comment: Some commenters raised concerns with the requirement in paragraph (d)(1) about communication that is effective with DLLs and their families. Some commenters were concerned about the rarity of certain languages and corresponding lack of interpreters or qualified teachers. Commenters pointed out that, in some instances, staff who speak the second language are sometimes not proficient in English and it is costly for programs to train them.

Response: The prior performance standards required that programs be able to communicate effectively with families, either directly or through an interpreter. This has been a long-standing requirement and expectation in Head Start. If program staff, interpreters, or translators do not speak all languages of the families in the program, then other support services should be utilized, such as interpretation services available via phone and other methods. We revised paragraph (d)(1) to take into account those extremely limited circumstances where interpretation services are not available by phone and other methods and to clarify the requirement by including "to the extent feasible."

Comment: Some commenters raised concerns with the standard in paragraph (d)(2) that requires programs to have at least one staff member who speaks the home language of DLLs in classes where the majority of children speak the same non-English language. Commenters were concerned about the lack of qualified bilingual staff, particularly for infant groups. Some commenters asked whether a waiver will be available for this requirement, and how to find interpreters.

Response: The prior performance standards required that at least one staff member or home visitor speak the language of the majority of children in the class or home-based program. This has been a long-standing requirement and expectation in Head Start. When the majority of children speak the same language, we believe it is imperative that staff be able to provide the children with high-quality language experiences. There is not a waiver available for this requirement.

Section 1302.91 Staff Qualification and Competency Requirements

This section includes requirements for staff qualifications and competencies. We raised many staff qualifications over those in the previous performance standards, as required by the Act. In response to comments, we included some new staff qualification requirements for child and family services management staff, family services staff, and mental health consultants. We also restructured the section to improve clarity. We discuss comments and our responses below.

Comment: Some commenters offered general comments that addressed the entire section. Some requested guidance on how to measure sufficient knowledge, training, and experience, as it relates to requirements throughout this section. Other commenters suggested we require all staff in all program options to have the knowledge and ability to work with children with disabilities. Some commenters noted the need to fund and implement strategies with higher education to ensure degree and credential programs include appropriate coursework content specific to the infant, toddler, and preschool workforce. Other commenters suggested that the credential or degree requirements for bilingual staff be more flexible, as it is very difficult to find bilingual staff who are also qualified in early childhood education. Further, some commenters recommended we require programs to review state early childhood workforce requirements on a regular basis to ensure that Head Start's requirements support and enhance state-based career ladders.

Response: We revised paragraph (a) to integrate professional development to support program service staff so they have the knowledge, training, experience, and competencies to fulfill their roles and responsibilities. We think programs should be continuously supporting staff in fulfilling their roles and responsibilities. We also revised paragraphs in this section to expand competencies for teachers, assistant teachers, family child care providers, and home visitors to include working with children with disabilities and DLLs to support effective service delivery. While we recognize recruitment of bilingual staff who are qualified in early childhood education may be challenging, we believe children who are dual language learners need highly-qualified teachers in order to achieve meaningful child outcomes. Additionally, while we agree access to appropriate coursework and financing is critical for a well-trained workforce, many of these challenges are beyond the scope of this final rule.

Comment: Commenters generally supported our proposal, in paragraph (i) of the NPRM and now found in paragraph (b), to require Early Head Start and Head Start program directors hired after the effective date of this final rule to have at least a baccalaureate degree. Some commenters were concerned this requirement would make it too difficult for programs to hire and retain directors. Some commenters suggested we allow programs to implement an alternate approach, such as allowing time for directors to acquire appropriate degrees or restricting the requirement to new hires. Other commenters supported a stronger requirement for directors and suggested we require directors to have a master's degree. Some commenters suggested additional requirements regarding experience or competencies.

Response: We retained our standard to require at least baccalaureate degrees for program directors as proposed in the NPRM. We revised the minimum background experience requirement to include administration in addition to supervision of staff and fiscal management. However, we retained local flexibility to define other necessary experience and competencies including experience in early childhood.

Comment: Some commenters supported our standard in what was paragraph (h)(3) in the NPRM that allowed flexibility for programs to establish qualifications for their fiscal officer based on an assessment of their needs and secure regularly scheduled or ongoing services of a fiscal officer. Other commenters suggested that fiscal functions should be led by a qualified accounting professional with expertise in understanding the operational risks, the potential for misalignment of funding, and the financial reporting associated with federal funding.

Response: We revised the standard for fiscal officer qualifications, now found in paragraph (c), to clarify that programs must consider the fiscal complexity of their organization to ensure fiscal officers have sufficient knowledge and experience to fulfill their role. We also require newly hired fiscal officers to be certified public accountants or have a baccalaureate degree in a related field.

Comment: The NPRM did not specifically address qualifications for staff who manage family services, health services, and disabilities services other than to require in paragraph (a) that all staff and consultants have sufficient knowledge, training, and experience to fulfill their roles and responsibilities. The NPRM did not retain language from the previous program performance standards about disabilities and health managers because we thought it was vague and not helpful for programs. Some commenters opposed our approach and interpreted it to mean we were removing services area management. Commenters suggested we require all supervisors have a baccalaureate degree. Other commenters suggested we require all supervisory staff to have knowledge of and training on reflective supervision. Further, some commenters provided explicit suggestions for qualifications that the health services manager should be required to have, such as a minimum of an associate's or bachelor's degree in health, public health, nursing, or a related field, or an early childhood education degree with health-related certification or licensure. In addition, some commenters suggested qualifications for disabilities managers, including a bachelor's degree with a certification in early childhood special education or related field. Finally, some of these commenters also suggested adding competencies for disabilities managers, such as experience working in an early childhood education setting.

Response: We did not intend for the NPRM to signal the removal of service area management. Our goal in omitting references to service area management was to increase local flexibility to better meet the variety of needs in programs of differing size. However, we revised the rule to require degree qualifications for newly hired family services, health, and disabilities managers. Specifically, as stated in paragraph (d)(1), staff responsible for the management and oversight of family services, health services, and services to children with disabilities hired after the effective date of this rule, must have at a minimum, a baccalaureate degree, preferably related to one or more of the disciplines they oversee. Programs should not interpret this requirement to mean they must have different people for disabilities management, family services management, and health services management. Due to the varying sizes and complexities of program structures, we think programs must have the flexibility to decide on their own appropriate staffing patterns to meet these oversight and management responsibilities.

Comment: In what was paragraph (e) in the NPRM, we proposed minimum requirements for education coordinators, as required by the Act. Some commenters recommended phasing in a requirement for education coordinators to have a master's degree. Some commenters requested additional flexibility in the requirement, such as allowing the degree to be in elementary education or family studies or allowing relevant coursework combined with a degree in an unrelated field. Additionally, some respondents suggested that education coordinators should have experience working explicitly with the age group of the classes they oversee.

Response: We believe the requirement as written is sufficient to ensure high-quality services and retained this requirement as proposed, now found in paragraph (d)(2). We did not include additional flexibility since minimum requirements for education coordinators are set by the Act. We made small technical revisions.

Comment: We specifically solicited comments on the appropriate qualifications for Early Head Start teachers, which was described in paragraph (b)(1) and now is located at paragraph (e)(1). We received a variety of different recommendations. For example, some commenters suggested we retain requirements from the Act that Early Head Start teachers have at least CDA. Some commenters suggested the CDA is adequate only if staff work closely with a coach, and some commenters recommended we require an associate's degree in early education. Others recommended we require a baccalaureate, and some supported phasing in baccalaureate requirements. Some commenters supported allowing one teacher in an Early Head Start class to meet a higher qualification and for the second teacher to have the current CDA qualification. Some commenters requested clarification of the term "equivalent course work," and offered suggestions. Some commenters expressed concern that increasing qualifications would impact programs' ability to hire parents and other community members who accurately reflect and can address the culturally and linguistically diverse needs and experiences of children and families, particularly in programs serving rural, migrant, and tribal populations.

Response: We maintained the staff qualification requirements for Early Head Start as proposed. Lowering these requirements is beyond the scope of this rule because they are set by the Act. We did not raise the requirement to a baccalaureate degree, although we agree with recommendations from the National Academy of Sciences (NAS) report[120] that a lead teacher in every class with a bachelor's degree and demonstrated competencies is optimal. Grantees are encouraged to implement effective career and professional development models and might find it particularly effective to have at least one lead teacher with higher credentials and another teacher who meets the minimum qualifications. We do not define "equivalent course work" because different colleges and universities describe majors and classes in a variety of ways; programs must evaluate the content and relevancy of the individual courses their teachers have taken.

Comment: We specifically solicited comments on the appropriate qualifications for Head Start teachers. In general, commenters supported requiring bachelor's degrees for all Head Start teachers. Some commenters suggested that all staff working directly with children and families should have a bachelor's degree. Other commenters expressed concern about compliance with higher standards, given the difficulties they already face in finding appropriately credentialed staff. These commenters were especially concerned with adding new credential requirements without designated funding to achieve the higher standards. Some commenters requested we allow degrees to be in a related field such as elementary education or family studies. Some commenters suggested the teacher qualification requirements should mirror language of other federal programs that supports alternative pathways and demonstrated competencies in lieu of credentials. Others recommended partnering with the Department of Education on an early education TEACH campaign in order to recruit highly qualified teachers. Other commenters suggested allowing programs to use proxy indicators of competence such as years of experience, completed training, or CLASS scores as a way to maintain employment of individuals who do not meet degree requirements. Some commenters were concerned that the broad language of "equivalent coursework" may create unnecessary confusion in the field as to whether Teach for America candidates may be hired; and suggested that clarifying language be included in the final rule.

Finally, commenters described challenges in recruiting and retaining qualified staff members who speak the community's language and understand its nuances. These commenters expressed concern that increasing qualifications would impact programs' ability to hire parents and other community members who accurately reflect and can address the culturally and linguistically diverse needs and experiences of children and families, particularly in programs serving rural, migrant, and tribal populations.

Response: In paragraphs (e)(2) and (3), we maintained the staff qualification requirements for Head Start teachers as proposed and as required by the Act. Lowering these requirements is beyond the scope of this rule because minimums are set by the Act. The Act also does not grant us authority to allow exemptions or proxy indicators of currently employed teachers who do not meet qualification requirements. As noted earlier, we are in agreement with the NAS report that having teachers with a baccalaureate degree in every class is optimal.[121] We have updated the statutory reference in paragraph (e)(2)(ii) to include all of the alternative credentials, including Teach for America.

Comment: We received some comments on our requirement in what is now paragraph (e)(3) for qualifications for assistant teachers. Some commenters requested clarification on whether or not assistant teachers with a CDA credential must also be enrolled in a program leading to an associate or baccalaureate degree, or if assistant teachers without a CDA credential must be enrolled in either a degree program or CDA credential program. Some commenters suggested we should encourage assistant teachers to attain associate's degree as a career ladder towards becoming a teacher. Other commenters expressed concern that two years is not long enough for an assistant teacher to attain a credential or degree. Some commenters expressed confusion about the difference between teacher assistants and teacher aides.

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[120] Institute of Medicine (IOM) and National Research Council (NRC). 2015. Transforming the workforce for children birth through age 8: A unifying foundation. Washington, DC: The National Academies Press.

[121] Ibid.

Response: As required by the Act, the provision in paragraph (e)(3) requires Head Start assistant teachers have at least a minimum of a CDA credential or be enrolled in a CDA credential program to be completed within two years of the time of hire. We revised this provision to clarify that the minimum requirement also permits a state-awarded certificate that meets or exceeds the requirements for a CDA credential. While assistant teachers with a CDA credential or state-awarded equivalent are not required to be enrolled in a program that will lead to an associate or baccalaureate degree, assistant teachers that are enrolled in a program that will lead to such a degree meet the qualification requirements. We consider assistant teachers to be a second educational staff person working within a preschool setting who supports the teacher in implementing planned curricular activities with the children. A teacher aide is a third person who may or may not provide direct curriculum support.

Comment: We specifically solicited comments on the appropriate qualifications family child care providers, which was addressed in paragraph (g) in the NPRM and now is found in paragraph (e)(4)(i). Some commenters objected to our proposal in what is now paragraph (e)(4)(i) to shorten the timeline for family child care providers to attain credentials from two years to eighteen months. Conversely, some commenters suggested we require family child care providers meet the same qualifications as center-based teachers.

Response: We retained the requirements for family child care providers as proposed. We believe our requirement in paragraph (e)(4)(i) appropriately balances the need to strengthen requirements and acknowledge funding realities and the ability of higher education to support degrees in early childhood. We did not substantively revise the provision.

Comment: Some commenters suggested the requirement in what is now paragraph (e)(4)(ii) that a child development specialist have at a minimum, an associate degree in child development or early childhood education is too low, given their responsibilities. Some commenters requested we define "child development specialist" as it relates to family child care.

Response: We agree the work that child development specialists do with family child care providers to support high-quality service delivery in family child care settings, as described in § 1302.23(e) requires a higher level of expertise. Therefore we amended what is now paragraph (e)(4)(ii) to more clearly link the duties of the child development specialist as described in § 1302.23(e) and require child development specialists have a baccalaureate degree in child development, early childhood education or a related field.

Comment: Some commenters supported our focus on both staff qualifications and the staff competencies for teaching staff we described in what were paragraphs (b)(2) and (c)(2) and are now found in paragraph (e)(5). Some commenters suggested additional competencies for teaching staff including understanding the birth to five developmental continuum; partnering with and engaging parents in their child's education; effective team teaching; culturally and linguistically responsive practices; second language acquisition; administering assessments; and the capacity and desire to expand skills, knowledge and abilities.

Response: Programs have the flexibility to determine the appropriate competencies to ensure high-quality staff and program effectiveness within their own communities. However, we revised paragraph (e)(5) to add use of assessment and promoting the progress of children with disabilities and dual language learners.

Comment: Many commenters expressed concern with or opposed our proposal to require home visitors have at least a CDA in what was paragraph (f) in the NPRM. Concerns with our proposal included: it was more important to focus on home visitor skills; home visitors are already trained and certified in other home visiting curriculum and that a CDA would be an inefficient use of funds; time should be provided to allow home visitors to obtain a CDA; and our proposal would disqualify home visitors with sociology, psychology, or other possibly relevant degrees.

Some commenters supported our proposal for home visitors to have a minimum of a CDA, although some of these commenters suggested their support was conditional on additional funds to raise home visitor salaries accordingly. Some commenters suggested additional flexibility for staff to meet this requirement such as an alternative or equivalent credential. Many commenters recommended we revise the standard to allow the home visitor to have a CDA or equivalent coursework or be enrolled in coursework to earn a CDA. Some commenters suggested that the minimum requirement of a CDA was too low and recommended we require at least an associate's degree in early childhood, child development or a related field with equivalent coursework that could be attained within a realistic timeframe. Some commenters suggested we set a national percentage goal for home visitors with bachelor's degrees.

Response: We believe our minimum requirement of a CDA for home visitors, now found in paragraph (e)(6)(i) is reasonable and in fact, given the complex nature of their work, that it is preferable for such staff to have an associate's or baccalaureate degree in a relevant field. We revised this requirement to clarify the credentials necessary for this position. In order to allow adequate time for staff to obtain a CDA, we are delaying the requirement to comply with this provision for two years. We also revised competency requirements in paragraph (e)(6)(ii) to include supporting children with disabilities and DLLs, and building respectful, culturally responsive, and trusting relationships with families.

Comment: The NPRM required all staff, including family services, health, and disabilities staff, to have sufficient knowledge, training, and experience to fulfill their roles and responsibilities. It did not retain vague language from the prior program performance standards about family services, health, and disabilities staff. We specifically requested comments on specific degree requirements for these staff. We received comments in support and opposition of our approach. Some commenters praised our removal of these provisions, and stated it would increase local flexibility for programs to set their own qualifications and better address their professional needs. Other commenters disagreed, and instead suggested we at least restore the previous requirements and suggested we include new degree competencies and qualifications, such as a minimum of a baccalaureate. Some commenters provided specific recommendations for strengthening qualifications for family service workers, such as a requirement that they, at a minimum, have an associate's degree in social work or a related field.

Response: We agree with the concerns commenters raised about child and family services staff and made revisions accordingly. We added a new requirement in paragraph (e)(7) to require newly hired staff who work on family partnership services have at least a credential or certification in social work, human services, family services, counseling or a related field within eighteen months of hire. We believe it is optimal for these staff to have an associate's or baccalaureate degree in a related field. We restored health professional qualification requirements in paragraph (e)(8)(i), and we expanded requirements for competencies to include assistant teachers and family child care providers in paragraph (e)(5).

Comment: Some commenters offered suggestions for the requirement for mental health consultants in what is now paragraph (e)(8)(ii). Some requested clarification about what it meant to "support" mental health services. Some commenters suggested mental health consultants be licensed or certified, demonstrate specific competencies, or have a degree in social work, professional counseling, or marriage and family therapy. Other commenters opposed the requirement that a mental health consultant be licensed or certified, citing inadequate funding.

Response: We think it is important that mental health consultants are licensed or certified mental health professionals so they have the training needed to provide the appropriate scope of services to young children and families. To strengthen the standard, we revised what is now paragraph (e)(8)(ii) to require that mental health consultants have, to the extent possible, knowledge of and experience in serving young children and their families. We also removed the language that referenced staff who "support" mental health services to improve clarity. We did not address other suggested requirements, because we believe that local programs need flexibility to determine the best approach to ensure mental health consultants are able to meet child and family needs.

Comment: Some commenters requested clarification for our use of the term "nutritionist" in what is now paragraph (e)(8)(iii). Commenters were concerned it could be interpreted to include a person who lacks formal education or training in the area of nutrition. Some commenters suggested we require registered dieticians and licensed nutritionists oversee all nutrition services.

Response: We believe the requirement that nutrition services be provided by registered dieticians and nutritionists is sufficient to ensure high-quality services.

Comment: Some commenters suggested we modify staff qualification requirements for migrant and seasonal and American Indian and Alaskan Native programs because these programs often find it difficult to hire staff with either credentials or degrees. For example, some commenters recommended we broaden the requirement for using child development specialists with associate's degrees in family child care to apply to migrant and seasonal programs because of challenges to find bilingual qualified staff in rural communities. Commenters recommended we allow migrant or seasonal Head Start programs to have lower staff qualifications than other Head Start programs and help them obtain degrees.

Response: Although we understand the challenges migrant and seasonal and American Indian and Alaskan Native programs face, we require these programs to hire qualified staff to work with children. However, we encourage programs to implement individualized professional development plans for all staff.

Comment: Some commenters suggested we add specific qualifications for coaches, such as a minimum of a bachelor's degree in in early childhood education or child development. Some commenters suggested we require coaches to demonstrate specific areas of knowledge, skills, and experience.

Response: We agree that in order for coaches to effectively support education staff they should have a minimum of a baccalaureate degree in early childhood education or a related field. Therefore, we have added a requirement in paragraph (f).

Comment: Some commenters requested clarification about teachers and providers working within community child care partnership sites need to meet the staff qualification requirements. They stated that increased requirements for Early Head Start programs could harm partnerships with community child care programs.

Response: Teachers and family child care providers must meet staff qualification requirements. Grantees funded with EHS–CC Partnership funds are allowed 18 months following receipt of the award to help staff attain the required credentials or degrees.

Section 1302.92 Training and Professional Development

In this section, we describe requirements for staff training and professional development. We require a coordinated system of professional development, including individualized coaching for all educators, including family child care providers. Commenters generally supported our integrated systems approach, and noted support for our more individualized professional development. Others cited research in support of our coaching requirements. We made revisions to strengthen professional development and training for all staff and to improve clarity of coaching requirements. We discuss these and other comments below.

Comment: Some commenters opposed our decision to omit a previous standard for staff performance appraisals because they stated these appraisals are an important way to identify professional development needs and to provide data to develop a training and technical assistance plan.

Response: We do not believe we need specific requirements for the process by which programs assess staff. Instead, we focused this section on requiring programs to implement a system to ensure all staff members receive the supportive training and development they need to provide high-quality services. Programs that value staff performance appraisals may continue to use this method as part of their system. We did not revise this provision.

Comment: Some commenters expressed concerned about the burden of "all day" orientations for program consultants.

Response: Paragraph (a) requires programs to provide an orientation to all new staff, consultants, and volunteers. We did not include any reference to "all day" or any prescribed length of orientations. We feel the intent of the provision is clear as written. Therefore, we did not revise this provision.

Comment: Many commenters expressed concern about the requirement in what was paragraph (b) about training and professional development having academic credit, as appropriate. Commenters recommended we revise the requirement to include continuing education units (CEUs). Some commenters misunderstood the intent of the requirement, pointing out that training on CPR, Sudden Infant Death Syndrome (SIDS), etc. could not bear academic credit.

Response: Paragraph (b) requires programs establish and implement a systematic approach to staff training and development. We did not intend to require that all staff training within the required system provide academic credit. Rather, academic credit should be sought, when appropriate, for such training and staff development in order to support staff progress toward degrees and other goals. We did not revise this provision.

Comment: Some commenters requested clarification about whether coaching hours would count toward the requirement for 15 clock hours of professional development. Some commenters expressed concerns that coaching hours will not be eligible for state registry professional development trainings.

Response: We consider coaching hours applicable toward meeting the 15 clock hours of professional development per year, assuming the coaching hours are designed to assist staff in increasing knowledge and acquiring new skills to help them provide high-quality services within the scope of their job responsibilities. Whether coaching hours are eligible for state registries is beyond the purview of this rule.

Comment: Some commenters request that parent engagement strategies be included in training and professional development.

Response: We revised what was paragraph (b)(2) and is now paragraph (b)(3) to require training for all staff on best practices for family engagement strategies. In addition, to appropriately address professional development for child and family services staff who are not education staff, we included a new requirement in paragraph (b)(4) to require training for family services, health, and disabilities staff to build on their knowledge, experience, and competencies to improve child and family outcomes. We also amended paragraph (b)(5) to include partnering with families as an area of the professional development for education staff.

Comment: Some commenters suggested there were disparities in training opportunities between lead teachers and teacher assistants.

Response: We believe it is important for the entire teaching team to receive appropriate training and professional development. Paragraphs (b)(5) and (c) require research-based approaches to professional development for all education staff, which includes assistant teachers.

Comment: Some commenters requested the training and professional development system explicitly include additional subjects, such as physical activity, outdoor play, positive behavior supports, and children with disabilities.

Response: We revised what is now paragraph (b)(5) to include partnership with families, supporting children with disabilities and their families, and use of data to individualize learning experiences. We did not include other revisions to broaden the focus of the requirement. This paragraph appropriately emphasizes professional development for education staff on the central aspects of effective teaching. We think it is important this section focus on these key skills for education staff. Programs can choose to provide professional development on other topics if they determine it best meets the needs of the children and families they serve.

Comment: Many commenters were concerned about our requirement in what is now paragraph (b)(5) to require research-based approaches to professional development for education staff. Commenters expressed a variety of concerns, such as cost, and requested further clarification about the term "research-based approaches." Other commenters supported our emphasis on research-based professional development and noted this was important to improving Head Start quality.

Response: We believe effective professional development is central to the delivery of high-quality education services that foster strong child outcomes. We think the requirement in paragraph (b)(5) is important to ensure program quality. There is existing guidance at at the Early Childhood Learning and Knowledge Center (ECLKC) [122] about research-based approaches professional development and professional development. We believe this a reasonable minimum threshold that will ensure programs are able to demonstrate outcomes for teacher development. Therefore, we did not revise this provision.

Comment: We received many comments on our proposal to require coaching be a part of the research-based approaches to professional development. Many commenters opposed it because of concerns such as cost. Some commenters strongly supported it, and pointed to research that demonstrated its importance in high-quality implementation and strong child outcomes. Some commenters stated the requirement was too prescriptive and placed too much burden on programs, especially rural programs, and staff. Other commenters requested we include more specificity and requirements for the proposed coaching systems, such as additional qualifications or expanding the requirement beyond education staff. Commenters also requested additional clarification, such as a definition of "intensive" coaching or which staff members are covered by the coaching requirement. Some commenters requested clarification about whether coaching could include online, remote and video supported coaching or if the requirement could be phased in, in order to build the capacity of coaching over time.

Response: We revised the structure of the coaching requirements to improve clarity. Coaching requirements are now found in paragraph (c) instead of paragraphs (b)(4) and (5) in the NPRM. We restructured these requirements to improve clarity, made revisions to the structure of this section and specifically to paragraph (c) to clarify the coaching requirements apply to education staff, and revised paragraph (c)(1) to incorporate a strengths-based approach. In paragraph (c)(1), we require programs to implement a research-based coordinated coaching strategy that assesses all education staff to identify their strengths and areas of needed support and to identify which staff would benefit most from intensive coaching. In paragraph (c)(2), we require programs to provide intensive coaching to, at a minimum the education staff identified as most benefiting from intensive coaching. In paragraph (c)(3), we require programs to provide other forms of research-based professional development to education staff who do not receive intensive coaching. In paragraphs (c)(4) and (5), we require specific elements of the coaching system.

The intent of these requirements is to ensure all programs utilize research-based coaching strategies, whether the strategies are employed via online or video supported methods is up to the grantee to determine. We acknowledge there are costs associated with implementing coaching strategies, but think is important for high-quality service delivery. We believe we appropriately balance local flexibility with requirements to include basic features that research indicates will support progress. The requirement allows programs flexibility to define much of the structural and goal setting aspects of their coaching strategy, including staffing patterns. Moreover, the effective date of the coaching requirement is delayed for approximately one year after this rule is published so programs have sufficient time for effective implementation. Additionally, we revised what is now paragraph (d) to add more flexibility to address concerns that the coaching provisions were too prescriptive.

Comment: Commenters requested we include language in coordinated coaching strategies in what is now paragraph (c) about a range of embedded professional development approaches.

Response: Paragraph (c)(2) requires intensive coaching for a subset of staff members. Paragraph (c)(3) requires programs provide other forms of research-based professional development to education staff who do not receive intensive coaching.

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[122] *http://eclkc.ohs.acf.hhs.gov/hslc/tta-system/pd/pds/Mentoring/edudev_art_00050_081105.html.*

Section 1302.93 Staff Health and Wellness

This section includes requirements for staff health and wellness, including staff health checks to ensure child safety and standards to support staff wellness. We discuss comments and our responses below.

Comment: We received many comments on the standards in paragraph (a) that address initial health examinations and periodic reexaminations for staff members. Some commenters requested clarification about the tuberculosis screening requirement in paragraph (a) for the initial health examination, including why it is the only mandatory screening. Other commenters recommended we revise paragraph (a) to describe the purpose and aspects of the initial health exam and others offered suggestions about the periodic re-examination. Some commenters recommend we include a reference to the Health Services Advisory Committee (HSAC) in this section. Many commenters stated that paragraph (a) conflicted with state requirements and would therefore make some collaborations difficult.

Response: We revised paragraph (a) to be consistent with state, tribal, and local laws, which will support collaborations. We also struck the specific requirement for screening for tuberculosis and instead reference that health examinations include screenings or tests for communicable diseases, as appropriate. This provides local flexibility to respond to local health needs and meet applicable requirements. We think it is too prescriptive to define how often a health re-examination should occur and did not prescribe the required timeframe. We also do not think it is necessary to prescribe requirements related to occupational health exams. Programs may want to use recommendations for doctors, jurisdiction, or the HSAC. We did think it was necessary to reference the HSAC in this section.

Comment: Some commenters recommend the standard in paragraph (b) should be strengthened to include activities beyond making mental health and wellness information available. For example, commenters suggested we broaden the focus of health and wellness or add a new standard for a daily staff health check. Some commenters recommend we note that an Employee Assistance Program could be used to implement these standards. Some commenters noted staff compensation contributed to stress and mental health problems and should be addressed.

Response: We agree we should strengthen paragraph (b), but that most of the specific suggestions were too prescriptive. We also believe it is important for programs to have flexibility to develop their own approach to ensure staff wellness. We revised paragraph (b) to specify that programs must provide regularly scheduled opportunities to learn about health topics. Staff compensation is outside the purview of this regulation. We agree that the Employee Assistance Program could be helpful but do not think it is appropriate to prescribe that level of specificity.

Section 1302.94 Volunteers

This section includes requirements related to the utilization of volunteers. We address comments below.

Comment: Some commenters recommended that we provide a definition for a regular volunteer and some commenters suggested we require volunteers receive an orientation on program and class procedures.

Response: We revised the requirement in paragraph (a) about screening for communicable diseases to be consistent with staff requirements in § 1302.93. What constitutes a regular volunteer can vary by program so we did not define this term. Section 1302.92(a) already requires volunteers to receive an orientation on the goals and underlying philosophy of the program and on the ways they are implemented. We think this is sufficient.

Program Management and Quality Improvement; Subpart J

This subpart establishes the roles and responsibilities for a program's management system and sets requirements for a data-driven management system for continuous improvement toward high-quality service delivery. It also sets forth requirements for the implementation of this rule. We received many comments on this subpart, most of which address the timeline for implementation of the final rule. Other commenters offered positive feedback on the management requirements or requested technical changes for clarity. We discuss the comments and our rationale for any changes to the regulatory text in this section.

General Comments

Comment: Some commenters supported our requirement that programs implement a coordinated approach to serving DLLs and offered further suggestions to increase the focus on DLLs throughout program management. Specifically, these commenters suggested requirements for programs to identify DLLs as a focal point of the process of ongoing monitoring and self-improvement for achieving program goals in § 1302.100. Commenters also requested a revision to § 1302.101(b)(2) to indicate how their coordinated approach should be evaluated. Finally, commenters suggested revising § 1302.102 to require programs set goals related to first and second language development for DLLs.

Response: The requirements in this subpart apply to all children, including special populations. This subpart also ensures the intentional implementation of a coordinated management approach for the full and effective participation of children who are DLLs and their families. We do not believe it is necessary to further emphasize particular populations within individual requirements throughout program management.

Section 1302.100 Purpose

This section provides a general requirement for programs to implement management systems and a process of ongoing monitoring and continuous improvement for achieving program goals. Aside from the overarching comment related to DLLs discussed above, we did not receive comments on this section.

Section 1302.101 Management System

This section describes the implementation of a program's management system by requiring regular and ongoing staff supervision to support continuous program improvement. This section also outlines requirements for programs to establish coordinated approaches to ensure professional development, services for dual language learners, services for children with disabilities, and data management. We received many comments on this section, including suggestions for strengthening management system requirements and requests for clarification.

Comment: We heard from commenters about the proposal to remove the requirement to have written plans for management systems. Some commenters opposed the removal of written plans, suggesting they are critical to building effective management systems. Other commenters praised the elimination of the written plans, noting that the removal of this requirement would reduce unnecessary bureaucracy. Still other commenters requested guidance or clarification regarding the removal of this requirement.

Response: We agree programs may find written plans to be valuable. We expect these programs will continue to use written planning to coordinate their management systems and ensure that all staff are able to fully implement them. However, the intention of removing written plans as a requirement is, as some commenters noted, to shift the focus from compliance with prescribed plans to monitory progress toward goals. We did not restore this requirement.

Comment: Some commenters suggested that, for clarity, we eliminate the phrase ''adequate record keeping'' in paragraph (a) and create a new standard to address record keeping so that all of the requirements in paragraph (a) were not explicitly linked to record keeping.

Response: We agree and untethered adequate record keeping from the other provisions in paragraph (a) and instead added a new paragraph (a)(4) to reflect this requirement.

Comment: Some commenters suggested revisions to the reference to promoting continuity of care in paragraph (a)(3). Some commenters thought it should be deleted because it is already covered by the full range of services described in subparts C through H. Other commenters suggested this requirement be linked directly to services for infants and toddlers.

Response: We believe continuity of care is critically important, and therefore we emphasize it in this section, despite its representation throughout the broader set of standards. Further, while we agree that continuity of care is of particular importance to infants and toddlers, we believe it is also important for preschoolers. Therefore, we did not revise this requirement.

Comment: Some commenters suggested we specifically include reflective supervision, particularly for Early Head Start staff, as part of the regular and ongoing supervision required in paragraph (a)(2).

Response: We require programs to implement research-based professional development in subpart I and regular and ongoing supervision under this subpart. Reflective supervision could be a component of both of these strategies. Therefore, Early Head Start programs may use reflective supervision if it helps them to ensure continuous quality improvement. However, we believe local flexibility for individual programs to determine the best approach to ensuring their management system provides regular and ongoing supervision, as long as the approach is research-based and effectively supports achieving program goals. Therefore, we did not revise this requirement.

Comment: Some commenters supported and others opposed the requirement that programs integrate Head Start data with other early childhood data systems and work with the state's K–12 Statewide Longitudinal Data System (SLDS) to share relevant data. Most of these commenters expressed concerns about the burden for programs to participate in their state's SLDS and recommended that it should be encouraged to the extent practical but not required. Commenters also expressed concerns with the varied capacity of states to partner effectively with Head Start providers to share, use, and interpret data which leads to barriers for programs to participate such as poor data infrastructure in the state's SLDS, statutory roadblocks, or lack of an SLDS in the state. Commenters stated that programs should not be held fully responsible with SLDS integration since it is beyond the abilities of most individual Head Start programs. Commenters also requested we advocate for the SLDS to send reports and information to programs that participate with their SLDS. One commenter recommended that tribes be explicitly exempt from any requirement to participate in their state's SLDS.

Response: We revised and reorganized the standards previously provided in § 1302.101(b)(4)(iii) to § 1302.53(b)(3). There, we clarified that a program should participate in their state education data system to the extent practicable and only if the program can receive the same support and benefits as other participating early childhood programs. Since state education data systems can vary greatly from state to state and the practicality of a program to participate in these systems can also vary, we provided programs flexibility as steps are taken to share data with their state within their capacity and existing supports provided. Regarding an exemption for tribes, we agree and added that AIAN programs are exempt from any requirement to participate in their state education data systems, unless an AIAN would choose to participate in the statewide data system to the extent practicable. Further, in paragraph (b)(4), we clarified that AIAN programs can determine whether or not they will participate in such data systems.

Comment: Commenters expressed concern with the requirement proposed in § 1302.101(b)(4) of the NPRM to align data collections and definitions to the Common Education Data Standards (CEDS) due to the burden on programs (*e.g.,* time, additional staff, and expense), and some commenters indicated that the responsibility to align with CEDS should not be on any individual program. Some commenters stated that the definitions in CEDS are not appropriate for all Head Start programs. Some commenters requested guidance on how to fulfill this requirement.

Response: We agree it is premature to promulgate standards encouraging programs to engage with CEDS since the early childhood data standards are not as far into development as the K–12 standards and there is insufficient information on the benefits and utilization of CEDS at the individual school level or early childhood setting. Additionally, CEDS is meant to be voluntary. As a result, we removed this standard.

Comment: Some commenters requested that programs be allowed to disclose PII from child records to the SLDS administrator to facilitate data sharing with the SLDS.

Response: According to § 1303.22(c)(2), a program is allowed to disclose PII from child records without parental consent to federal or state officials, in connection with an audit or evaluation of education or child development programs, as long as the program maintains oversight of child records through a written agreement or other means. Therefore, officials representing a state entity that manages a state education data system, such as an SLDS, would fall under this description and a program would be allowed to disclose the necessary PII to such an official.

Comment: Some commenters opposed the requirement of a data governance body or council described in paragraph (b)(4) and stated that it is an excessive and costly requirement. Some commenters were in favor of the requirement. Commenters also requested clarity on the definition of this group, including its purpose, role, and function; how it differs from other governing groups, specifically the board of directors, policy council, and governing board; and whether it applies to Early Head Start programs.

Response: We believe programs have established systems that focus on the security of data, an important goal, but this has overshadowed effective data sharing with other relevant entities. We shifted the focus to encompass a balance between the security, availability, usability, and integrity of data through these provisions. However, commenters misinterpreted our intent, primarily due to the terminology used. Therefore, we changed the term ''data governance'' to ''data management'' in this paragraph and we removed the reference to a ''body or council'' to focus less on the process and more on the desired outcome of establishing procedures to ensure data quality and effective data use and sharing, while protecting the privacy of child records. For this same reason, we also removed the requirement to consult with experts and advisors on early childhood data systems in their state. Programs are still encouraged to do this but including it as a standard distracts from the overall focus on outcomes instead of process. To clarify that this requirement also applies to Early Head Start, we changed "Head Start data" to "data."

Comment: A commenter requested we require programs to align their data systems with one another.

Response: We disagree with this suggestion. Programs use multiple data systems and not every data system used can or should be aligned. For example, a data system used for salaries, wages, and fringe benefits would not align with a data system for the administration of children immunizations. Thus, requiring programs to align their data systems is too broad of a requirement and could create more complications than benefits.

Section 1302.102 Achieving Program Goals

This section describes the program goal setting process with respect to quality improvement. It is reorganized from the previous rule to better convey the importance of establishing goals for effective health and safety practices, all elements of high-quality service provision, and continuous quality improvement for all programs, not just those with identified quality issues or deficiencies. It includes requirements for each aspect of the cycle of continuous quality improvement including planning; goal setting; and monitoring short- and long-term progress towards achieving goals. This section also describes reporting requirements as they relate to ongoing monitoring and self-assessment. Commenters made a number of recommendations for strengthening this section, and we made small changes to the language for clarification throughout the section. We discuss specific comments and responses below.

Comment: Some commenters recommended we require a system that sets benchmarks for child and family outcomes, based on nationally normed assessment measures, and outlines strategies for tracking progress in order to support program improvement efforts, professional development, and evaluation. These commenters suggest that such a system would better ensure children enter school performing on par with their more advantaged peers.

Response: We believe that it is important for programs to have local flexibility to set their own goals and measure children and families' progress towards those goals. We do not think it is appropriate for us to set a single standard all programs must use to assess the continuous improvement of their program.

Comment: Commenters requested we require programs to set goals for the outcomes of educational and other services, rather than for the provision of these services. Some commenters also suggested that programs should be required to set goals for the recruitment, retention, and development of qualified staff. Other commenters suggested we reduce the types of program goals that are required. These commenters stated that too many goals would prevent programs from being able to focus and achieve desired outcomes.

Response: We believe we have achieved an appropriate balance for the goal-setting requirements. We encourage programs to set additional goals if it helps them effectively meet the needs of their community and ensure continuous quality improvement. The intent of this requirement is to set a minimum.

Comment: Many commenters requested programs be allowed to align revisions to their goals, as described in paragraph (a), with their five-year grant cycle.

Response: While we understand that programs may wish to revisit their goals, especially their long-term strategic goals described in paragraph (a)(1) with their five-year grant cycle, we feel continuous quality improvement requires programs to thoughtfully re-evaluate their goals on an ongoing basis. Additionally, the replacement of the *Head Start Child Development and Early Learning Framework* for three to five-year-olds with the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* should result in a re-evaluation of programs' school readiness goals to ensure they are promoting the school readiness of all children in all domains. We did not revise this provision.

Comment: Many commenters praised the clear link of the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* (HSELOF) to school readiness goals in paragraph (a)(3). Other commenters requested we allow programs to align with both HSELOF and their state early learning standards. Further, some commenters expressed confusion about the relationship between performance goals and school readiness goals.

Response: The requirement in paragraph (a)(3) is for all programs to align with both HSELOF and their state early learning standards, where state standards are applicable. We previously issued guidance describing the relationship between school readiness goals and program goals. This guidance clarifies that school readiness goals are a subset of program goals. However, we agree that the terminology "program performance goals" is confusing. Therefore, we revised the term throughout subpart J to "program goals." We also re-ordered the list of goals that programs must establish in this section to reflect a hierarchy of goals, starting with broad, strategic long-term goals.

Comment: Many commenters noted that the monitoring system will need to be aligned with the outcomes-focused approach to continuous quality improvement described in the section, and the requirements in paragraph (b).

Response: The monitoring process will be revised to align with these program performance standards.

Comment: Commenters offered suggestions for strengthening data use for continuous quality improvement in paragraph (c). Some commenters recommended we include requirements for best practices in using data to improve instruction, including how often data must be reviewed and used to inform services. Others suggested strengthening requirements for continuous improvement by referencing feedback loops, which they thought would allow programs to be proactive rather than reactive. These commenters also suggested that programs should be required to develop and implement policies and procedures that guide staff collaboration on the review, interpretation, and use of data to advance policy and practice improvements and professional learning goals.

Response: We do not agree that we should set such specific requirements for the process by which individual programs ensure continuous quality improvement. Rather, we focus on requiring programs to implement a system to ensure continuous quality improvement but leave the details of how each program will achieve this up to local communities to determine.

Comment: Some commenters suggested we require additional areas of data collection, aggregation and analysis to ensure continuous program improvement in all areas of program services. Suggestions included adding family engagement, home visits, group socializations, and staff development. Some commenters suggested that the requirement included too many areas for data collection, aggregation, and analysis, stating that grantees need to be able to focus their efforts on a limited set of specific goals for program improvement.

Response: We believe we have achieved an appropriate balance for data requirements. Programs are encouraged to collect additional data, as necessary, in order to inform their own goals and ensure continuous quality improvement. The intent of this requirement is to set a minimum for service areas grantees must collect data on.

Comment: Some commenters stated that it is inappropriate to aggregate data for infants and toddlers, especially in small programs with very few children in similar developmental age ranges, or that it is inappropriate to directly assess infants and toddlers three times per year.

Response: The requirement to aggregate and analyze child-level assessment data three times per year in paragraph (c)(2)(ii) is not new. Guidance already exists on the topic of assessment and data aggregation for infants and toddlers and can be found at *http://eclkc.ohs.acf.hhs.gov/hslc/tta-system/ehsnrc/school-readiness/SchoolReadiness.htm*. This guidance clarifies that aggregation and analysis of data is possible for infants and toddlers and does not have to done by child age. Further, we revised paragraph (c)(2)(ii) to refer programs to the definition of child-level assessment data in part 1305, which includes observation-based as well as direct assessments. We believe this change addresses concerns about frequent direct assessment of infants and toddlers.

Comment: Some commenters noted that we should add an exception for programs less than 90 days to the requirement to aggregate and analyze data three times per year.

Response: We agree and revised paragraphs (c)(2)(ii) and (iii) and a requirement in paragraph (c)(2)(iii) to clarify that programs operating for fewer than 90 days only have to aggregate and analyze their data twice per year.

Comment: Some commenters asked us to define "lessons" in paragraph (c)(iv), formerly paragraph (c)(2)(iii) in the NPRM.

Response: We revised the requirement to read "information," rather than "lessons" to clarify our intent.

Comment: Some commenters requested we provide justification for requiring reports.

Response: The Secretary has broad statutory authority under section 641A(a)(1) of the Act to establish standards to ensure the health and safety of children and appropriate program operation.

Comment: Many commenters suggested that the requirements in paragraph (d)(1)(ii), formerly paragraph (d)(1)(iii) in the NPRM, were too vague. Specifically, many commenters requested clarity about what risks should be reported under paragraph (d)(1)(iii)(C) in the NPRM. As proposed, commenters suggested the requirement would include everything from chicken pox to a bite from a classmate to an outbreak of influenza at a nearby nursing home. Commenters also requested clarity on which reasons for program closure under paragraph (d)(1)(iii)(B) in the NPRM need to be reported. For example, commenters asked whether programs needed to report when they close due to inclement weather. Finally, commenters stated the requirement in paragraph (d)(1)(iii)(D) in the NPRM was too vague and requested clarity on what legal proceedings, involving which related parties, would need to be reported.

Response: We agree with commenters that the proposed requirements in paragraphs (d)(1)(ii) and (iii) in the NPRM were unclear and we made revisions to clarify our intent. We revised and restructured these standards into paragraph (d)(1)(ii) and struck paragraph (d)(1)(iii) to clarify that programs must report significant incidents, rather than "risks," related to health and safety or financial and administrative circumstances, to the responsible HHS official. Therefore, inclement weather closings, for example, would not apply to the requirement in what is now paragraph (d)(1)(ii)(B) and risks such as a nearby outbreak of influenza or minor incidents such as child biting a classmate are clearly not included. Finally, we revised what is now (d)(1)(ii)(C) to better clarify that we only require programs to report legal proceedings that are directly related to program operations.

Comment: Some commenters noted that the community assessment is too long to include in the annual self-assessment. These commenters suggested amending the requirement to include only a synopsis or summary of the most recent community assessment. Additionally, some commenters suggested that inclusion of the community assessment in the self-assessment should be aligned with each grantee's five-year grant cycle, such that grantees would only be required to include it when their grant cycle is being renewed.

Response: We revised paragraph (d)(2) to allow for a summary of the most recent community assessment to be included in the annual self-assessment. We also clarified that programs must be publish and disseminate the report.

Section 1302.103 Implementation of Program Performance Standards

This section includes requirements to ensure programs implement the program performance standards effectively and to provide flexibility to programs in meeting the requirements of subpart B, if any currently enrolled Head Start children could be displaced.

Comment: Many commenters requested consistent guidance, communication, and training and technical assistance to grantees related to the implementation of the final performance standards, and explicitly the move to full day programs.

Response: The final rule includes a compliance table that outlines that dates by which programs have to be in compliance with the new standards. It shows that many of the provisions go into effect 60 days after publication but that others, such as some of the provisions related to curriculum, assessment, and coaching, do not require compliance until August 2017 and that the requirement for a longer day and year are further delayed. We think this staggered phase-in timeline will give programs adequate time to implement these changes in a thoughtful way with support from OHS and our training and technical assistance system.

Financial and Administrative Requirements; Part 1303

This part lays out financial and administrative requirements for agencies.

Section 1303.1 Overview

This part specifies the financial and administrative requirements for programs consistent with various sections in the Act. Subpart A outlines the financial requirements; subpart B focuses on administrative requirements; subpart C implements statutory provisions related to personally identifiable data, information, and records; subpart D outlines the requirements for the operation of delegate agencies; subpart E implements statutory provisions related to facilities; and subpart F describes transportation requirements. We received comments on each of these subparts. We summarize comments and provide our response below.

Financial Requirements; Subpart A

This subpart reorganizes, revises, and streamlines the financial requirements in subparts A, B, C, and D of part 1301 in the previous performance standards. This purpose of these changes is to organize the requirements in a more logical order, conform to recent changes in regulations that govern all federal grants, and reduce the administrative burden on agencies.

Section 1303.2 Purpose

This section specifies that the purpose of this subpart is to establish requirements for program administration and grants management that apply to all grants under the Act. A summary of comments and our responses is below.

Comment: Some commenters were pleased we removed the accounting system certification we required in the previous performance standards at § 1303.11. They stated that it resulted in added cost for programs with limited or no gain.

Response: We agree the certification was an unnecessary burden to grantees and their financial professionals.

Comment: Some commenters suggested that we should not have removed the annual audit requirement in § 1301.12 of the previous performance standards. Many commenters recommended we clarify that an annual audit is still an allowable expense for programs of all sizes.

Response: The Office of Management and Budget establishes audit requirements and specified their requirement related to all federally required audits in the Uniform Guidance. Audits are a permissible expense regardless of program size. No changes to this section are necessary.

Section 1303.3 Other Requirements

This section displays in a chart an updated list of HHS regulations that apply to all grants made under the Act. We received many comments on this chart.

Comment: Commenters suggested we clarify what is required for issuance of a Dun and Bradstreet Data Universal Number System (DUNS) number and annual or reoccurring reporting requirements.

Response: We did not make changes in response to this comment. We believe that the cross-reference to 2 CFR 25.10 CCR (Central Contractor Registration)/DUNS provides grantees with sufficient DUNS information to support initial and ongoing compliance and reporting requirements.

Section 1303.4 Federal Financial Assistance, Non-federal Match, and Waiver Requirements

This section consolidates into one section the financial assistance, non-federal match, and waiver requirements that were in §§ 1301.20 and 1301.21 of the previous performance standards. We did not receive comments on this section but made two technical changes to the regulatory text in the final rule. First, we used the term "non-federal match" throughout, instead of "non-federal share match" or "non-federal share matching" to be consistent and to more closely align with the Uniform Guidance. Second, we modified the language to state that a waiver of all or a portion of non-federal match could be approved "for" the budget period instead of "during" the budget period. Since waivers after the close of the budget period are possible, we wanted to ensure the language reflects that allowable activity.

Section 1303.5 Limitations on Development and Administrative Costs

This section affirms the requirement in section 644(b) of the Act that agencies not exceed the 15 percent cap on development and administration. It also implements the requirement in section 644(b) of the Act that the Secretary establish criteria for determining the costs of developing and administering a program and the total costs of such a program. In contrast to § 1301.32(b) through (f) of the previous performance standards, this section represents a simplified and streamlined approach that requires grantees to categorize, identify, and allocate costs in order to determine whether they meet the 15 percent administrative cap. This section also specifies the requirements related to waivers of the cap on development and administration.

We received comments on this section and made one technical change to the regulatory text in the final rule. We removed the language requiring that a waiver not exceed 12 months to provide for the possibility of longer budget periods like those used for the Early Head Start-Child Care partnerships.

Comment: Some commenters believed it would be helpful if we train grantees on how to appropriately identify development and administrative costs. Other commenters suggested we increase the limit on administrative and development costs we proposed in paragraph (a)(1) of this section.

Response: We did not increase the limit on administrative and development costs specified in paragraph (a)(1) because it is established in the Act. Training is available on how to identify administrative and development costs.

Administrative Requirements; Subpart B

This subpart outlines the requirements for agency conduct, the limitations and prohibitions to which agencies must adhere, and the requirements for insurance and bonding.

Section 1303.10 Purpose

This section specifies that grantees must observe standards of organization, management, and administration and conduct activities in a manner consistent with the Act. We received comments related to these general requirements.

Comment: Some commenters supported the requirement that grantees observe stated standards of organization, management and administration but urged us to include a new standard that requires employers to pay living wages, or provide compensation levels at parity with elementary school teaching staff or the average compensation level for comparable work in the area.

Response: We did not change this requirement. We continue to require grantees to establish wages that are comparable to those paid in their community based on the wage comparability provision in the Act.

Comment: Some commenters expressed concern that we eliminated previous language that required each agency to provide reasonable access to information and records.

Response: We believe the issue of access to information and records is already adequately addressed by other applicable federal and state law and a Head Start specific provision is not necessary.

Comment: Some commenters asked that we consider equipment to be any item with a value of $25,000 or more.

Response: The fiscal regulations at 45 CFR part 75 govern the definition of equipment and we cannot adopt contrary requirements in these regulations.

Comment: Some commenters requested we allow agencies with Head Start and Early Head Start awards to prepare a single budget.

Response: Head Start and Early Head Start awards use separate Central Accounting Numbers (CANs) and fiscal regulations require separate accounting for those funds.

Section 1303.11 Limitations and Prohibitions

This section consolidates into one place the sections in the Act that place limitations or prohibitions on agencies. These sections pertain to union organizing, the Davis Bacon Act, limitations on compensation, nondiscrimination, unlawful activities, political activities and obtaining parental consent. We received comments on this section.

Comment: Some commenters recommended removal of the requirement that programs comply with the Davis-Bacon Act or requested that we limit the application of the Davis-Bacon Act to new major projects only.

Response: The Act requires compliance with the Davis-Bacon Act, including the definition of covered projects. We cannot eliminate this requirement through the regulatory process.

Comment: Some commenters suggested that Head Start program employees should not be allowed to engage in union organizing.

Response: Section 644(e) of the Act states that Head Start funds may not be used to assist, promote, or deter union organizing. We retained this prohibition in this section by referencing the Act.

Section 1303.12 Insurance and Bonding

This section requires that grantees maintain a documented process to identify risks and provide proof of appropriate coverage in their grant application. Our approach to require grantees to assess their own risks and determine appropriate cost-effective coverage is a less prescriptive approach that section § 1301.11 of the previous performance standards. We received comments on this section.

Comment: Some commenters said removing specific requirements for insurance provides too much leeway, creates risk of liability and that appropriate coverage should be defined, with a minimum threshold or reference to state child care licensing requirements and suggested we remove the requirement that the process of identifying risks consider the risk of losses resulting from fraudulent acts by individuals authorized to disburse Head Start funds.

Response: We did not change this requirement in response to comments. We believe that implementation of an intentional risk assessment process is an important aspect of grantee fiscal viability and may dictate varying amounts of insurance coverage depending on the grantee's unique circumstances. We believe assurance that Head Start funds are not lost to fraudulent acts is an important part of identifying risks.

Protections for the Privacy of Child Records; Subpart C

This subpart outlines the requirements for programs to ensure the protection of child records, including requirements for parental consent and instances where disclosure of children's personally identifiable information (PII) without parental consent is allowable. We added standards that ensure the protection of the confidentiality of PII contained in child records. These standards align with the policies, protections, and rights found in the Family Educational Rights and Privacy Act (FERPA), as appropriate for Head Start and Early Head Start programs. We received comments on all sections of this subpart. Overall, commenters were supportive and positive about these standards, especially the alignment to FERPA and the emphasis placed on parent rights in respect to their child's record.

Section 1303.20 Establishing Procedures

This section outlines required procedures that support the sections that follow on confidentiality of PII in child records. We respond to the comments we received below.

Comment: Commenters requested clarification on whether programs are required to have procedures for parents to inspect a child's record or challenge the sharing of the child's PII, and suggested we reference this subpart in subpart D Health Program Services to ensure programs consider the privacy of child records in health program services.

Response: According to § 1303.20, a program must establish procedures to protect the confidentiality of any PII in child records. As part of these procedures, programs must ensure parents have the right to inspect, ask to amend, and obtain copies of their child's records, request hearings, and inspect written agreements. This subpart is not specified in subpart D since the protections of the privacy of child records should be considered throughout the entire final rule. We also added breaches of PII to the issues that programs must report in § 1302.102(d)(1)(ii).

Comment: Commenters requested federal support and training opportunities on this subpart to ensure proper implementation, especially for programs without a deep understanding of privacy rules and while programs link data to their state and federal data systems. Some commenters recommended we require capacity building for data privacy as part of staff training.

Response: We are committed to providing support for programs to understand, build capacity, and comply with the new privacy regulations. Programs must ensure staff, consultants, and volunteers comply with program confidentiality policies in accordance with § 1302.90(c)(1)(iv).

Section 1303.21 Program Procedures—Applicable Confidentiality Provisions

In this section, we describe in paragraph (a) that when FERPA's confidentiality requirements apply (*i.e.*, for educational agencies and institutions that maintain education records), the confidentiality requirements in this subpart do not apply because those educational agencies and institutions must comply with FERPA. Similarly, we describe in paragraph (b) that the Head Start confidentiality requirements in this subpart also do not apply when IDEA's confidentiality provisions apply (*i.e.* a program collects, uses, or maintains early intervention records of infants and toddlers with disabilities referred to or eligible under Part C of the IDEA or education records of children with disabilities referred to or eligible under Part B of the IDEA). Therefore, the Head Start confidentiality requirements in this subpart do not apply to the records of those children covered by IDEA or programs covered by FERPA. Commenters raised specific concerns and requested clarity, and our responses are discussed below.

Comment: Commenters requested we provide guidance and clarity on how other privacy laws apply including state laws and the Children's Online Privacy Protection Act (COPPA).

Response: A program must comply with other applicable federal, state, or local privacy laws such as COPPA, which applies to all programs, the Children's Internet Protection Act (CIPA) which applies to programs in the E-Rate program, and the Protection of Pupil Rights Amendment (PPRA), which applies to programs administered by the U.S. Department of Education (ED) receiving federal funds.

Comment: Some commenters expressed concern that it will be burdensome and confusing for some programs to comply with FERPA and this subpart, and that we make this subpart consistent with FERPA or provide guidance on how to comply with both.

Response: We agree that we are not duplicating under Head Start the confidentiality protections that already apply under FERPA and IDEA. The provisions we are promulgating are very similar to FERPA. However, we want to reiterate that when programs comply with FERPA or IDEA for the records of those children and programs covered under FERPA and/or IDEA, then this subpart does not apply. Thus, we are eliminating any perceived burden and duplication. We changed and restructured the language in this section to implement these provisions.

Section 1303.22 Disclosures With, and Without, Parental Consent

In this section, we describe provisions programs must follow to protect the privacy of child records and to share data. Most commenters in this section made recommendations or requested clarifications related to specific needs of Head Start programs, which are discussed below.

Comment: Commenters recommended several changes to this section to reflect FERPA, such as: Add an exception to parental consent for disclosing PII classified as "directory information"; include the entire criteria in FERPA on a written agreement; remove the term "disaster" from § 1303.22(c)(4); add other FERPA requirements on the disclosure of PII without parental consent for a lawfully issued subpoena or judicial order; require the class of recipients be specified within the consent form; and permit disclosure without parental consent to a school the child intends to enroll or is already enrolled.

Response: We intended to align this section with FERPA while meeting the needs of Head Start and Early Head Start programs, and therefore a direct replication of FERPA would not be appropriate. In regards to directory information, we believe that a list of names, addresses, photographs, and other information that may fall under directory information can be harmful if disclosed without parental consent for the vulnerable population we serve, and therefore no change was made. In regards to the written agreement, our intent is for the program to determine the reasonable method to maintain control appropriate for the disclosure including a written agreement, direct supervision, and/or other methods. We updated § 1303.22(c)(1) through (3) to focus on our intent which provides programs flexibility without being overly prescriptive. In regards to "disaster," the term refers to an emergency such as a natural or manmade disaster. We agreed with the recommendations to include the class of recipients in the consent form and to permit disclosure in compliance with a subpoena without consent, similar to what FERPA permits, and these changes have been made. Lastly, the disclosure without parental consent related to a child's enrollment or transfer is already addressed in § 1303.22(b), and parental consent is not required.

Comment: Commenters recommended we add clarify, replace, or define terms in this section including, "dependency matters" as this could refer to any case involving a dependent child and an adult caregiver, "case plan," and "foster care." Commenters expressed concern that these terms could differ from state to state.

Response: We disagree on defining dependency matters. However, it is not our intent that any case involving a dependent child and an adult caregiver inherently involves dependency matters, so we clarified that the court proceedings must directly involve dependency matters. Foster care is defined in part 1305. The definition for "case plan" was added to part 1305.

Comment: Commenters expressed concern that posting child allergy information prominently as described in § 1302.47(b)(7)(vi) violates the privacy of children.

Response: We believe it is critical that food allergies are prominently displayed in areas wherever food is served to mitigate a serious health and safety risk for infants, toddlers, and preschool aged children. We also believe programs should be able to address other serious health and safety risks without parental consent to disclose PII. As a result, we added a "serious health and safety risk such as a serious food allergy" to § 1303.22(c)(4) of this section.

Comment: Some commenters recommended that violators of the privacy rule be given the opportunity to self-correct before any sanctions are applied.

Response: Any violations of the privacy rule will be handled through existing monitoring and Head Start enforcement mechanisms.

Comment: Commenters requested an exception to release PII without consent in the case of reporting child abuse or neglect if they are required to do so by law.

Response: States receiving funds under the Child Abuse Prevention and Treatment Act (CAPTA) from HHS are required to enact laws mandating the reporting of known and suspected instances of child abuse and neglect. States must also ensure that the disclosure is made only to persons or entities determined by the State to have a need for the information. To ensure this section of the regulation does not conflict with federal, state, local, or tribal laws that require reporting of child abuse or neglect, we added § 1303.22(c)(8) which allows the disclosure of PII without parental consent to an appropriate party to address suspected or known child maltreatment to comply with applicable federal, state, local, or tribal laws on reporting child abuse and neglect. We do not specify the persons who may access the records and under what circumstances since these vary by state.

Comment: Commenters expressed concern that a program would apply the five-year rule that used to appear in § 1303.22(d) automatically after a single violation of a written agreement which could lead to conflicts with state and local mandatory reporting requirements; that barring third parties from accessing child records for any violation of the written agreement is too broad; and the annual review of the written agreement seems arbitrary.

Response: We agree with the concerns on the five-year rule, and we modified the provision to allow a program greater flexibility in handling third party violations. A program must review the written agreement annually, but only update it if necessary.

Comment: Commenters expressed concern that programs will not be allowed to share data with partners critical to Head Start programs such as community partners, health partners, contractors, consultants, subrecipients, and volunteers. Commenters requested that we clarify data sharing with community partners; the term "educational interest"; and the term "official."

Response: A program may disclose PII from a child record without consent to a partner if the partner meets one of the conditions in § 1303.22(c). A partner will most likely qualify as an "official acting for the program" if they are directly or indirectly providing program services for which the agency would otherwise use an employee. If a community partner does not qualify under any condition in § 1303.22(c), we recommend programs build written consent into the enrollment process for these partners. We removed "educational interests" and replaced it with plain language for clarity. We added language to § 1303.22(c)(1) through (3) to clarify the term official.

Section 1303.23 Parental Rights

In this section, we focus on parents' rights. We recognize that parents should be at the forefront when it comes to the collection, use, and sharing of the PII in respect to their child's record. Most commenters in this section supported the rights provided to parents. Other commenters raised concerns, which are discussed below.

Comment: Some commenters requested we provide an additional requirement for programs to annually inform the parent on what data are being collected, how and why the data are used, and how the data are being safeguarded.

Response: The parental consent form coupled with the annual notice already provides this information to the parent. We believe that requiring details on each data element collected, how each is used and for what exact purpose, and the specific security measures taken to protect the data would be excessive and burdensome.

Comment: Commenters both agreed and disagreed with informing parents of their rights annually due to the conflicting perceived level of effort required by the program. Another commenter noted a conflicting requirement that allowed a parent the right to obtain a copy of the child record even when court ordered the contents related to disclosure not be disclosed or when it involves a child abuse or neglect case.

Response: We believe that it is important that the program annually notify parents of their rights. However, this notification does not necessarily need to be individualized for every parent. For instance, the program could include a standard handout as part of the material the parent will already receive during the program year. This flexibility reduces burden on programs. In regards to the conflicting information, we added language in § 1303.23(d) to ensure the parents' right to a copy of a record does not conflict with a court order.

Comment: Some commenters expressed concern with programs making decisions on how to effectively share data and what specific data to share.

Response: We agree that it can be challenging for programs to make decisions about how to share data and what data to share. Programs may request guidance through the training and technical assistance system. Additionally, we did not intend for programs to share all PII during a disclosure, therefore we added § 1303.22(f) to limit the program to only disclose the PII that is necessary for the purpose of the disclosure.

Section 1303.24 Maintaining Records

In this section, we describe recordkeeping requirements related to the protection of child privacy. Programs must maintain, with each child's record, a list of all individuals, agencies, or organizations that obtained access to PII from child records. The list must indicate the expressed interests that each person, agency, or organization had to obtain this information. Recordkeeping of disclosures to program officials or parents are not required since it would be too burdensome for programs. Programs must ensure that only parents, officials, and appropriate staff have access to records. We received some comments on this section, discussed below.

Comment: Some commenters requested we provide the amount of time a child record must be maintained and how IDEA relates to record maintenance.

Response: Depending on the type of data involved and the context in which the data are being used, there may be requirements for destruction of data with which programs must comply. We do not address information about other applicable program requirements, including those that may apply under IDEA, as that is beyond the scope of this regulation, but note that programs may be subject to record retention requirements for children they are serving based on applicable Federal and State statutes of limitations. However, when no other requirement exists, a program must destroy child records within a reasonable timeframe after the child has been served—this was added to § 1303.24(a). We also added a restriction to data destruction in § 1303.23(a)(4) to protect the parental right to inspect a record.

Comment: Some commenters pointed out an inconsistency between the NPRM preamble and proposed regulatory text. Specifically, for § 1303.24(b), the NPRM preamble required a program maintain information of all requested access to PII from child records, but the proposed regulation stated that information on these parties is only maintained when a disclosure of PII is actually made. The commenters preferred the proposed regulatory text.

Response: We agree that programs must only maintain this information when a disclosure is actually made. It is not necessary to maintain records on each request for PII from child records if the program does not make a disclosure of PII in response to the request.

Delegation of Program Operations; Subpart D

This subpart consolidates previous performance standards on delegation of program operations into one section and revises requirements to conform with the Act. Section 641A(d) of the Act requires agencies to establish procedures that relate to its delegate agencies and that provide further specifics related to evaluation, corrective actions, and terminations. We discuss and analyze the comments on this section below.

Section 1303.30 Grantee Responsibility and Accountability

In this section, we clarify that a grantee is accountable for its delegate agencies. That means the grantee retains legal authority and financial accountability for the program when services are provided by delegate agencies. Consequently, the grantee must support and oversee delegate agencies and ensure they provide high-quality services to children and families and meet all applicable regulations. We also clarify a grantee may not terminate a delegate agency without showing cause and must establish a process for delegate agencies to appeal adverse decisions. We discuss the few comments we received on this section below.

Comment: One commenter stated the phrase "bears financial accountability" in the fourth sentence in this paragraph, implied the grantee was responsible for any financial debt a delegate incurred. The commenter recommended we clarify the grantee bears responsibility for those allowable transactions it authorizes that are directly related to the Head Start program provided by delegate agencies.

Response: When the phrase "bears financial accountability" is taken in context of the entire section, it implies the grantee is responsible for the use of Head Start funds by the delegate. Therefore, we did not make any changes to this section.

Comment: One commenter asked us to allow programs to terminate delegate agencies "at will" with provisions that cause the least amount of undue stress and harm as possible to children and families served.

Response: We did not allow grantees to terminate delegate agencies "at will." Grantees can only terminate delegate agencies, if the grantee shows cause why termination is necessary and the grantee's decision to terminate cannot be arbitrary or capricious.

Section 1303.31 Determining and Establishing Delegate Agencies

Under this section in the NPRM, we proposed to require an agency that enters into an agreement with another entity to serve children to determine if the agreement meets the definition of "delegate agency" in section 637(3) of the Act. We proposed this performance standard to clarify that if an entity meets the definition of delegate in the Act, it is a delegate, regardless of what a grantee calls the entity to which it has delegated all or part of the responsibility for operating the program.

Comment: The NPRM proposed a requirement for HHS to approve the delegate agency before the grantee may delegate program operations. One commenter suggested that a delegate agreement be considered as approved if HHS had not approved or denied it 60 days before the program year starts.

Response: We believe HHS approval of delegates is important. We did not change the requirement.

Comment: One commenter asked whether or not programs could grandfather in existing delegate relationships or must they still have written agreements.

Response: All grantee/delegate relationships must have written agreements approved by the responsible HHS official. This is not a new provision.

Comment: Some commenters asked us to differentiate between "delegate agency" and "contractors." Another commenter asked if partners and family child care homes were considered delegates and if so does the grantee provide appeal procedures of the agreement is terminated. If family child care homes are considered delegates, the commenter recommended for us to add the following language to paragraph (a) to clarify that a grantee, partner, or family child care home can mutually agree to decline a delegate/grantee relationship: ". . . unless the grantee and the entity negotiate to form a contractual rather than a delegate relationship." This will provide flexibility to the entity regarding the requirement to form a policy committee or other delegate responsibility.

Response: A "delegate agency" is a public, private nonprofit (including a community based organization, as defined in section 9101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801), or for profit organization or agency to which a grantee has delegated all or part of the responsibility of the grantee for operating a Head Start program. Generally, a "contractor" either performs work or provides goods at a certain price or within a certain time.

We did not make any changes to paragraph (a) in this section. Family child care providers do not meet our definition for "delegate agency" because they do not meet the first part of that definition. They are our partners under the Early Head Start Child Care Partnership (EHS–CCP). Under EHS–CCP, new or existing Early Head Start grantees partner with regulated center-based or family child care providers who agree to meet Head Start program performance standards.

Section 1303.32 Evaluations and Corrective Actions for Delegate Agencies

This section includes requirements from section 641A(d) of the Act with respect to the evaluation of delegate agencies and corrective actions in the event of a deficiency.

Comment: Some commenters asked us to include the actual language of section 641A(d) of the Act rather than cite to it and to clarify that the Act's requirement for each Head Start agency to establish procedures to evaluate and defund delegate agencies and for delegate agencies to appeal defunding decisions may be satisfied with provisions on those topics in its delegate agency agreement(s).

Response: We refer to the Act when possible to streamline and to make the regulation read better. We did not make any changes to this section.

Section 1303.33 Termination of Delegate Agencies

In this section, we clarify that a grantee cannot terminate a delegate agency without showing cause and the grantee's decision to terminate cannot be arbitrary or capricious. To align with section 641A(d)(1)(C) of the Act, we require grantees to establish procedures to defund a delegate agency. We also require grantees to establish procedures that are fair and timely for a delegate agency to appeal a defunding decision.

Furthermore, we removed the appeal procedures for delegate agencies that were under part 1303 subpart C in the previous rule. The reason being, grantees are accountable for the services their delegate agencies provide to children and families. We believe they must have the necessary tools at their disposal to remove delegate agencies. We believe the previous system inappropriately tied the hands of grantees and had become overly burdensome.

We address the comments we received on this section below.

Comment: Some commenters supported our proposal to eliminate complex delegate agency appeals procedures. They believed this provided helpful flexibility to Head Start agencies that, for reasons of cost or inadequate delegate agency performance, may find it necessary to terminate a delegate agency relationship.

Response: We agree that grantees are ultimately accountable for their delegates. Consequently, grantees must be able to remove delegates when necessary, without having to go through an overly burdensome process. Furthermore, we believe grantees are in the best position to provide appeal processes for delegate agencies. We have not changed this provision.

Facilities; Subpart E

This subpart implements the statutory requirements related to facilities in section 644(c), (f), and (g) of the Act. It clarifies and reorganizes requirements for grantees when they apply to use Head Start funds to purchase, construct or make major renovations to facilities.

This subpart logically organizes all relevant information and requirements for protecting the federal interest under a broad variety of circumstances. It also removes requirements that are not Head Start-specific but rather are overarching requirements for managing federal grants and aligns all remaining provisions with the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. We address comments we received on each section within this subpart below.

Section 1303.40 Purpose

This section clarifies that the whole of subpart E applies to major renovations. It explains these provisions apply only to minor renovations and repairs when they are included in a purchase and are part of the purchase costs. We address the one comment we received on this section below.

Comment: One commenter noted that it may be necessary to us to clarify that information contained in a Program Instruction and its application be made clear in this section.

Response: We integrated the information from Program Instructions into this section and into our definition for "purchase" in part 1305. We did not make any changes here.

Section 1303.41 Approval of Previously Purchased Facilities

Our previous regulation did not address refinancing. But as interest rates have fallen, grantees have asked us for permission to apply for more advantageous loan terms. In this section, we allow grantees that have purchased facilities beginning in 1987 and that continue to pay purchase costs or seek to refinance indebtedness to apply for funds to meet costs associated with refinancing. We also revised the language to clarify that a purchase includes both principal and interest payments on approved loans in accordance with section 644(g)(2) of the Act. We received comments on this section and address them below.

Comment: One commenter asked why we included ''1987'' in this section.

Response: The ''1987'' date is consistent with the Act. The date notes it is allowable to use funds to purchase or continue the purchase of facilities after December 31, 1986. We revised the language to more closely mirror the Act.

Comment: One commenter asked us to remove language that requires grantees to obtain HHS permission to refinance an existing mortgage.

Response: We did not remove language that requires grantees to get HHS permission to refinance an existing mortgage. Refinancing of existing indebtedness may result in cross-collateral or cross-default provisions that put facilities subject to a federal interest at risk of foreclosure for debt not associated with the Head Start program.

Section 1303.42 Eligibility To Purchase, Construct, and Renovate Facilities

This section prescribes what grantees must show to be eligible to construct or renovate a facility. It also clarifies grantees that apply for funds to purchase, construct or renovate a facility must establish that the facility will be available to Indian tribes, rural, or other low-income communities. We received multiple comments on this section. We address those comments below.

Comment: Commenters suggested we clarify in paragraph (a) how a grantee can establish that preliminary eligibility requirements are satisfied.

Response: We did not revise language in this section to prescribe how a grantee can establish preliminary eligibility to purchase, construct, or renovate a facility. We believe that a grantee may demonstrate preliminary eligibility in a variety of ways and that a prescriptive process might create compliance challenges for some grantees.

Comment: Some commenters felt we created an unnecessary cost burden because we require a certified appraiser to address availability of suitable facilities in paragraph (b) of this section. These commenters believed a real estate professional's opinion was sufficient.

Response: We agree availability of suitable facilities can be adequately established, at lower cost, by an independent real estate professional familiar with the local commercial real property market. Therefore, we revised paragraph (b) to clarify a real estate professional's opinion is sufficient.

Section 1303.43 Use of Grant Funds To Pay Fees

This section clarifies the type and extent of pre-project costs, such as project feasibility studies and professional fees, we may approve before a grantee applies for funding to purchase, construct, and renovate facilities.

Comment: One commenter asked us to revise this section to allow grantees to use funds from their then-current Head Start grant for facilities projects or apply for and receive funds under the noted section.

Response: We did not revise this section to allow grantees to use existing grant funds for fees and costs associated with a facilities project. We believe that can be addressed through existing facilities regulations at 45 CFR part 75.

Section 1303.44 Applications To Purchase, Construct, and Renovate Facilities

This section focuses on the process grantees must use to apply for funds to purchase, construct, and renovate facilities. We address comments we received on this section below.

Comment: One commenter queried whether the facilities application process is applicable to all uses of funds for facilities activities or only when additional funds are requested. Another suggested we should add a performance standard that requires the responsible HHS official to promptly review and make final decisions regarding completed applications under this subpart.

Response: General language in § 1303.40 refers to facilities purchased, constructed or renovated with grant funds and applies to all defined activities regardless of how funding is awarded. Therefore, we did not make changes here.

We also did not require the responsible HHS official to promptly review and make final decisions. The primary reason being facilities applications require substantial information and some applications are incomplete when submitted. The length of time the responsible HHS official may need to help a grantee submit a complete application and determine availability of funding varies.

Comment: One commenter noted in paragraph (a)(2) of this section a deed or proof of legal ownership should not be the sole requirement for renovations on leased facilities. Grantees should be able to present a proposed lease agreement.

Response: We currently require grantees to submit a proposed lease in paragraph (b)(1) in this section currently requires submission of a proposed lease agreement and landlord consent. A slight amendment was made to remove the requirement that the submitted copy by an ''official'' copy since leases are not subject to official certification.

Comment: One commenter contended value appraisals for major renovations to leased properties were an unnecessary expense. The commenter also suggested we should allow grantees to submit bids and/or procurement documents in lieu of appraisals.

Response: Since a grantee does not obtain title to leased property subject to major renovations, we agree that an appraisal is not needed in that limited circumstance. We revised paragraph (a)(7) accordingly. However, we did not revise paragraph (a)(7) to allow grantees to submit bids and/or procurement documents in lieu of appraisals. We believe a licensed appraisal to establish value ensures consistency and accuracy.

Comment: One commenter suggested we should eliminate the required Phase I environmental assessment of proposed facilities sites in paragraph (a)(12) because remediation would increase project costs and prove to be an impediment to facilities projects on leased property. Another commenter suggested we should not require environmental assessments for major renovations.

Response: We did not remove this performance standard. We rely on environmental assessments to ensure we only fund those activities that result in safe and healthy care environments for children, families and staff whether the facility is owned or leased.

Comment: One commenter asked us to reduce the lease term requirement for modular units on property not owned by the grantee from 15 years to 10 years.

Response: Modular units often represent a substantial expenditure. We believe that a lease term of 15 years will assure grantees have a location for the modular unit for a period of occupancy long enough to use the full value of the federal investment in the modular unit.

Section 1303.45 Cost Comparison To Purchase, Construct, and Renovate Facilities

We require grantees to compare costs to renovate, to lease an existing facility, or to construct a new facility to determine which activity would be most cost effective to meet program needs. Grantees must be able to demonstrate that they have compared costs and weighed options so we know our investment in a particular facility activity is cost-effective and service-relevant. This section allows grantees greater flexibility to describe projects and to compare costs to other alternatives within their service areas.

We address the one comment we received on this section below.

Comment: One commenter asked us to revise the last sentence in paragraph (a)(1) in this section so that it refers to a "comparable alternative facility."

Response: We did not revise paragraph (a)(1). We believe the term "alternative," allows for the possibility of a non-comparable facility, such as one that might be made usable through major renovations.

Section 1303.46 Recording and Posting Notices of Federal Interest

This section focuses on federal interest and clarifies when grantees must file notices of federal interest and what the notices must contain. We address comments we received on this section below.

Comment: Some commenters contended grantees would not be able to file federal interest notices until the purchase, construction, or major renovation was either complete or at least when these activities have begun or when a grantee obtains ownership or begins occupancy.

Response: To protect federal interest in acquired facilities or in facilities undergoing major renovations with federal funds, we believe the notice of federal interest must be filed as early as possible to avoid the superior placement of liens for materials and services that would compromise priority of the federal interest. Therefore, we did not revise paragraphs (b)(1)–(3).

Comment: Some commenters felt the performance standard in paragraph (b)(4) that requires grantees to post the notice of federal interest on the exterior and the interior of modular units, could be cost prohibitive.

Response: We did not revise paragraph (b)(4). Posting the notice of federal interest on the exterior of the property informs all third parties that there is federal interest in the property. The exterior notice of federal interest for a modular unit can be as simple as a single-page laminated weatherproof copy of the interior notice firmly attached to the exterior of the modular unit, which would involve minimal cost.

Comment: Commenters liked our streamlined definition for "major renovations," but asked us to either define or clarify what we mean by "federal interest."

Response: We agree our former definition for "major renovations" was difficult for grantees to apply.

We did not change our definition for "federal interest," because we believe it fully advises grantees of when a federal interest is created and how property that is being used to meet non-federal match is treated. We believe what we mean by "federal interest" is more detailed and complete in this final rule.

Section 1303.47 Contents of Notices of Federal Interest

This section comprehensively explains what notices of federal interest must contain when a grantee owns a facility, when a grantee leases a facility, and when a grantee occupies a modular unit. We received some comments on this section, which we address below.

Comment: One commenter asked us to strike the term "or minor" from paragraph (a)(4).

Response: We revised paragraph (a)(4) to remove the phrase "or minor" because minor renovations or repairs are not subject to this subpart unless they are part of a purchase.

Comment: One commenter recommended we remove the performance standard in paragraph (a)(8) that requires the governing body to formally approve the notice of federal interest because it was unnecessarily prescriptive.

Response: We believe as the entity fiscally and legally responsible for the grantee, the governing body should be made aware of any notices of federal interest the grantee files. However, given the governing body must approve all facilities applications, we agree they do not also need to approve the notice of federal interest. We revised paragraph (a)(8) accordingly.

Comment: Commenters asked us to clarify whether a recorded lease could serve as a notice of federal interest. Other commenters noted the reference in paragraph (b)(1)(vi) of this section to notices of federal interest on leased property should have referred to § 1303.50(b)(1) through (4). Another commenter stated landlords may be unwilling to lease to Head Start grantees if a notice of federal interest for major renovations to leased property is required.

Response: We revised paragraph (b)(1)(vi), so it is clear a recorded lease that includes requisite provisions can serve as a notice of federal interest for leased property subject to major renovations. We also revised paragraph (b)(1)(vi) so that it references paragraph (b)(1)(i) through (v).

Finally, we did not revise this performance standard to accommodate situations where landlords may be unwilling to lease to Head Start grantees if a notice of federal interest for major renovations to leased property is required. We believe requiring recognition of the federal interest resulting from major renovations in lease agreements filed in the public record protects the ongoing use of improved properties for Head Start purposes during the useful life of the improvements financed with Head Start funds.

Comment: Commenters asked us to clarify what the word "proof" in paragraph (c)(3) meant.

Response: We replaced the word "proof" with the phrase "[A] statement that."

Section 1303.49 Protection of Federal Interest in Mortgage Agreements

Funding for facilities often includes both federal funds and mortgage proceeds. As funding for facilities has become more complex, it is common to find federal funds and mortgages on the same property. In order to protect federal interest, we require grantees to ensure that any mortgage agreements they have include specific provisions that would mitigate our risk of loss and ensure the property remains for Head Start purposes.

This section prescribes what mortgage agreements must contain. We address comments we received on this section below.

Comment: Commenter indicated the term "a real property . . . agreement" made paragraph (b) in the section unclear. The commenter asked us to reference any default under "an agreement described in § 1303.49(a) instead.

Response: We revised paragraph (b) accordingly.

Section 1303.50 Third Party Leases and Occupancy Arrangements

Grantees may use federal funds to renovate leased property, often at substantial cost. This section requires grantees to have leases in place for 30 years for construction of a facility and at least 15 years for a renovation or placement of a modular unit to protect federal interests in these unusual cases where the government is putting major costs into facilities on land that they do not own. We address comments we received on this section below.

Comment: Some commenters asked us to not apply paragraph (a) in this section to existing leases that did not meet term requirements.

Other commenters suggested there should be a flexible approach to lease term lengths that depended on the cost of the facilities project, individual circumstances of the grantee, community and nature of the facilities project or, that we adopt a fixed period of 10 years. Some commenters also noted that five-year grant cycles did not align with 15 or 30 year leases.

Response: We revised paragraph (a) to clarify that its terms did not apply to existing leases prior to the effective date of the regulations. We did not take a flexible approach to lease term lengths. Given that facilities activities involve substantial Head Start funds and are intended to be available for Head Start use as needed during the useful life of the facility, we made lease term lengths consistent. We also set term lengths to ensure grantees are subject to comparable lease term length requirements, regardless of location. Finally, we believe long term occupancy agreements for the full useful life of major renovations and purchases are needed to protect the Head Start funds used for major renovations and purchase of facilities located on leased property.

It is understood that migrant and seasonal Head Start programs may not utilize leased premises for entire program years. However, given the high dollar cost of major renovations and purchase of facilities, we believe that long term occupancy agreements, even if for limited portions of the program year, are needed. If a facility is no longer needed for program purposes, grantees can request disposition of the leasehold interest in the property.

Section 1303.51 Subordination of the Federal Interest

This section emphasizes that only the responsible HHS official can subordinate federal interest to a lender or other third party. Grantees cannot subordinate federal interest on their own. The HHS official must agree to subordination in writing. In addition to a written agreement, the mortgage agreement or security agreement for which subordination is requested must comply with § 1303.49, and the amount of federal funds already contributed to the facility must not exceed the amount provided by the lender seeking subordination. We address comments we received on this section below.

Comment: Commenters indicated that limiting subordination of the federal interest to circumstances where the amount requested exceeds the amount of federal funding in the property would result in reluctant lenders.

Response: We revised this performance standard to integrate the possibility of subordination to a lesser debt if certain conditions are met.

Section 1303.52 Insurance, Bonding, and Maintenance

Our experience has demonstrated that grantees have not maintained sufficient insurance for replacement of facilities that are substantially damaged or destroyed, particularly through floods and other natural disasters. After Hurricane Sandy, we realized we had to be more vigilant to protect grantees against loss.

In this section, we require grantees to obtain flood insurance if their facilities are located in areas the National Flood Insurance Program defines as high risk. We also clarify for grantees that physical damage or destruction insurance must cover full replacement value.

We address comments we received on this section below.

Comment: One commenter noted that the cost of flood insurance should be included in the Cost and Savings Analysis so as not to create an unfunded mandate upon the grantee.

Response: We did not make any changes here because flood insurance is an allowable cost to the Head Start award and can be included in the grantee's application for funding.

Comment: One commenter asked us to revise paragraph (b)(3) to read, "A grantee must submit to the responsible HHS official, within 10 days after coverage begins, copies of applicable certificates of insurance."

Response: We revised paragraph (b)(3) to clarify what insurance coverage must be proven but leaves it to the grantee to choose what documents to present to prove coverage.

Section 1303.53 Copies of Documents

This section adds notices of federal interest to the list of required documents grantees must provide to the responsible HHS official. It also requires grantees to give copies of notices of federal interest to the responsible HHS official after they have filed the notices in their jurisdiction's property records. This is particularly important because notices of federal interest do not fully protect the federal share until the notices are filed in the appropriate property records. We address comments we received on this section below.

Comment: One commenter was concerned that if we include leases in this section, we might create a situation wherein large numbers of leases would have to be reviewed annually.

Response: We do not require grantees to submit documents listed in this section annually. Furthermore, these documents are only necessary when related to purchase, construction or major renovation, so we believe the volume of submissions will be manageable. We revised this section to clarify these documents must be submitted when Head Start funds are used for the noted facilities activities.

Section 1303.54 Record Retention

This section clarifies what documents grantees must retain as records. This section does not change the basic retention period, which is aligned with general requirements in the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. We did not receive any comments on this section.

Section 1303.55 Procurement Procedures

This section summarizes general procurement procedures as context for grantees. We did not receive any comments on this section.

Section 1303.56 Inspection of Work

This section aligns the elements of the final inspection report with those required in the engineer or architect's certification that accompanies the initial facilities project application. We address comments we received on this section below.

Comment: One commenter recommended that we do not require project architects to certify compliance with regulations beyond his control such as licensing and Section 504 of the Rehabilitation Act.

Response: We did not make any changes here. We believe the project architect is a qualified professional familiar with the project, who can express an opinion as to whether a facility subject to purchase, construction or major renovation with Head Start funds meets all applicable federal, state, and local requirements.

Transportation; Subpart F

This subpart describes the requirements for programs related to transportation services. We received comments on this subpart. Some commenters supported the requirements in this section and stated that without transportation provided by the program, many high need families would be unable to access the program as they do not have private vehicles or access to public transportation. Other commenters expressed concerns or asked for clarifications. These comments are discussed in further detail below along with our responses.

General Comments

Comment: Some commenters asked about the applicability of the regulation including for field trips or transporting children and parents to medical appointments. Some commenters expressed concern about the cost of transportation services or specific elements, such as requiring bus monitors. One commenter asked about the relative cost, quality, and compliance of contractual versus directly provided transportation.

Response: Incidental transportation as described under the definition of "transportation services" in part 1305 is exempt from the requirements of this subpart. This includes taking a sick child home or taking a child and parent on a medical visit. Field trips are not incidental transportation and therefore are subject to the requirements of this subpart. Additionally, we recognize that providing transportation is expensive, but that many high need children would not be able to participate in Head Start without transportation services. No program is required to transport all or any children, but if high need families require transportation services to access the program, such services should be part of the program design. Programs should also regularly assess the cost and quality of their transportation service and make informed decisions about the safest and most cost efficient options. We did not make any changes to the regulation in response to these comments.

Section 1303.70 Purpose

This section describes transportation services and waiver options for programs. We received some comments on this section, which are discussed below.

Comment: Some commenters objected to the requirement in paragraph (b) that programs not offering transportation services make reasonable efforts to assist families who might otherwise have difficulty ensuring their child's participation. Some commenters indicated this provision could be especially difficult in rural areas and should therefore be removed. Some commenters requested more clarity about what constitutes "reasonable assistance."

Response: This provision is intended to ensure that programs that do not provide transportation ensure that lack of such service does not pose a barrier to participation in the program for the highest need children and families. Many rural Head Start programs, for example, provide transportation because not doing so would greatly limit the number of the highest need children who could participate. We expect that when a program has determined transportation is not a needed service, there are available alternatives. Therefore we retained this requirement, but added an example of reasonable assistance to paragraph (b).

Comment: One commenter suggested that programs must ensure compliance with the requirements of this subpart when obtaining Head Start transportation services by coordinating with another human service agency.

Response: We agree with this comment but do not think it requires a revision to the regulation. As defined in part 1305, Head Start transportation services include "the planned transporting of children to and from sites where an agency provides services funded under the Head Start Act." Therefore services provided through a coordinating agency would have to meet the requirements of this subpart. Each program is responsible for ensuring that the transportation services it provides, whether directly, through a coordinated effort with an LEA or community partner, or through a contractual arrangement, meet these requirements.

Comment: Some commenters asked for additional information about the circumstances under which a waiver can be issued and how decisions regarding waiver approval are made.

Response: Per the regulation, we will only consider waivers in circumstances where adherence to this subpart would create a safety hazard or, for preschool children, a major program disruption in relation to the requirements for child restraint systems or bus monitors, such that a waiver is in the best interest of enrolled children. We did not make any changes to these provisions. Typically, programs receiving transportation services through a partnership with a local education agency are the only ones approved for waivers. Programs can find information about applying for a transportation waiver through the Head Start Enterprise System (HSES) or by contacting their program official.

Section 1303.71 Vehicles

This section describes the requirements for vehicles used to transport children. We received some comments on this section, which are discussed below.

Comment: One commenter requested additional information about allowable alternate vehicles.

Response: The definition of "allowable alternate vehicle" is provided in part 1305 and refers to a vehicle designed for carrying eleven or more people, including the driver, that meets all the Federal Motor Vehicle Safety Standards applicable to school buses, except 49 CFR 571.108 and 571.131. It is a vehicle that may not look like a traditional school bus, but has the required safety features such as compartmentalized seating, rollover protection, joint impact strength, and fuel system integrity. We did not make any changes to this provision.

Comment: One commenter objected to the removal of the former requirement that safety equipment be strategically placed and marked.

Response: While we expect each program to store such equipment where it is safe from children but accessible in an emergency, we agree that such equipment should be clearly labeled. We amended paragraph (b) to specify this.

Section 1303.72 Vehicle Operation

This section describes safety requirements during vehicle operation, driver qualification and application review requirements, and requirements for driver and bus monitor training. We received some comments on this section, discussed below.

Comment: One commenter suggested that we allow reasonable accommodation related to the requirements of the commercial driver's license (CDL) and that drivers should follow applicable Department of Transportation (DOT) regulations, including for drug and alcohol testing.

Response: In addition to possessing an appropriate CDL, drivers providing Head Start transportation services must meet applicable DOT, tribal, state, and local requirements for their jurisdiction. There are requirements for drug and alcohol testing associated with a CDL. Therefore, we did not make any revisions to this provision.

Comment: Some commenters expressed concern that the requirement to review a driver candidate's record through the National Driver Register could delay the hiring of needed drivers.

Response: While we understand the concerns about the expediency of various background checks, we believe it is very important to use available sources that may provide information about the safety record of driver candidates. Therefore, we retained this requirement to check the National Driver Register where available.

Comment: One commenter expressed concern that standards articulated the requirement for child safety restraint systems, but did not actually require that children be seated while using them.

Response: We agree that safety restraint systems only afford protection if they are properly used. We amended § 1303.72(a)(1) to specify that each child should be seated in a child restraint system appropriate to the child's age, height and weight.

Comment: Some commenters referred to the requirement in paragraph (d) that drivers receive training in first aid. One suggested that Cardio Pulmonary

Resuscitation (CPR) also be required. Another suggested it is not necessary to require first aid training for drivers.

Response: We agree that drivers should have both first aid and CPR training. This is required in § 1302.47, and is therefore deleted from the list of training requirements in this section.

Section 1303.73 Trip Routing

This section establishes requirements for the safe and efficient planning of transportation routes.

Comment: Some commenters had concerns about the length of bus routes, including that some bus routes exceed an hour due to the geography of the service area and that complying with the trip routing safety requirements results in longer trips.

Response: Programs must keep trips under one hour, to the extent possible. We recognize that in some areas, such as rural areas, routes may be longer than an hour. We encourage programs to train bus monitors to provide meaningful interactions, discussion, songs, etc. with children during the time on the bus. We also understand that such things as requiring no U turns and curbside pick-up and drop off may extend routes. However, as the majority of school bus related child fatalities occur before boarding or after exiting the bus, we believe these safety provisions are necessary. We did not make any changes to these provisions.

Section 1303.74 Safety Procedures

This section describes the safety procedures programs must adhere to as part of transportation. We did not receive any comments on this section and therefore did not make any changes to these provisions.

Section 1303.75 Children With Disabilities

This section describes requirements for transporting children with disabilities. Below we discuss the comments we received on this section and our corresponding responses.

Comment: Some commenters supported the provision in paragraph (a) of this section that children with disabilities must be transported in the same vehicles used to transport other children whenever possible. Other commenters raised questions or concerns including a request to retain a previous provision to ensure special transportation requirements in a child's IEP or IFSP are followed, and a question about whether a program must ensure that drivers from other agencies are trained.

Response: In paragraph (b), we retained the provision that ensures special transportation requirements in a child's IEP or IFSP are followed; this provision was also retained in the NPRM. All Head Start transportation services, including those for children with disabilities, must meet the requirements of this regulation, whether they are provided directly, contractually, or through agreement with a local educational agency or other partner.

Federal Administrative Procedures; Part 1304

Monitoring, Suspension, Termination, Denial of Refunding, Reduction in Funding, and Their Appeals; Subpart A

This subpart focuses on monitoring, areas of noncompliance, deficiencies, and quality improvement plans. It outlines what happens when a grantee is suspended, when a grantee is terminated, when a grantee's financial assistance or application for refunding is denied, and when a grantee's assistance is reduced. It also clarifies the appeals process for certain adverse actions. We analyze the comments received on this subpart below.

Section 1304.1 Purpose

This section lays out the Secretary's authority to monitor whether grantees meet program performance standards and to prescribe notice and appeal procedures. We did not receive any comments on this section.

Section 1304.2 Monitoring

This section clarifies our authority to monitor grantees to ensure they comply with the Act, all program performance standards, and other federal regulations. We also clarify for programs that a deficiency can develop from an uncorrected area of noncompliance and from monitoring findings that show either a grantee's systemic or substantial material failure to comply with standards. We received comments from the public on this section and we discuss those comments below.

Comment: Some commenters urged us to take the lead to streamline Early Head Start, Head Start, and Child Care and Development Fund monitoring requirements and practices so that programs can focus more on performance and outcomes and less on monitoring compliance with detailed regulation. These commenters suggest for ACF to work more collaboratively with other federal partners to coordinate approaches to monitoring, and evaluating and supporting continuous quality improvement of early learning programs and their impacts. One commenter urged us to take the lead to build better integration between Early/Head Start data and state/local data systems.

Response: We will continue to work to better align Early Head Start, Head Start, and Child Care and Development Fund monitoring requirements and practices where possible. We will also continue to work with other federal partners to coordinate approaches to monitoring. We will continue to work with partners to facilitate better integration between Early/Head Start data and state/local data systems.

Comment: Some commenters asked us to define "immediate deficiencies," to prescribe how these deficiencies can be resolved, set time frames to correct areas of noncompliance and deficiencies, and, establish a deficiency review board that is independent of the regional office.

Response: We defer to the Act's definition for "deficiency," at section 637. Deficiencies are not determined at the regional level, though they were many years ago. Now, the Director of the Office of Head Start determines all deficiencies independently.

Comment: One commenter asked us to consider whether CLASS scores that fall below national norms, should be a non-compliance issue rather than a deficiency. The commenter believes data, including CLASS results, should be used as flashlight to illuminate paths to professional development and the central tenet of Head Start, continuous improvement.

Response: We did not propose any changes to the designation renewal system at former part 1307 in the NPRM. As we did not invite comments on the designation renewal system in the NPRM, we cannot respond to this comment here.

Section 1304.3 Suspension With Notice

This section includes the program performance standards for suspensions with notice. Although we retained, without change, most performance standards in this section, we proposed a few changes in the NPRM. We received comments on what we proposed in the NPRM and we address them below.

Comment: Some commenters complained paragraph (g) in this section gives the HHS official unilateral authority to impose additional suspensions indefinitely without having to verify in writing that deficiencies still exist. They argue that this practice conflicts with section 646(a)(5)(A) of the Act which requires the Secretary to prescribe procedures to assure that the Secretary may suspend financial assistance, "for not more than 30 days . . ." To comply with the Act, they asked us to remove the sentence: "Nothing in this section precludes the HHS official from imposing suspension again for an additional 30 days if the cause of the suspension has been corrected."

Response: Paragraph (g) in this section does not violate section 646(a)(5)(A) of the Act. If a grantee has not satisfactorily corrected what led to the suspension in 30 days, HHS has the ability to impose another suspension for 30 days.

Section 1304.4 Emergency Suspension Without Advance Notice

In this section, we discuss the circumstances that warrant emergency suspension without notice. We proposed a few small changes in the NPRM, specifically we added the term "emergency situation" to the reasons we can suspend without notice, to be more closely aligned with the Act. And we proposed to no longer allow grantees to use contributions during the suspended period to count toward in-kind match. We received comments on this section and discuss those comments below.

Comment: Some commenters believed paragraph (b) was worded awkwardly. To make the paragraph read better, the commenter asked us to make the following changes: Delete the phrase "by any means" in paragraph (b)(2); reword paragraph (b)(3); and clarify what the "informal meeting" is in paragraph (b)(4). The commenter also pointed out something was missing in paragraph (c).

Response: We revised the language in paragraphs (b)(1)(iv), (b)(2) and (3), and (c) for clarification.

Comment: Some commenters noted if we allow the responsible HHS official to impose additional 30 days suspensions, then in effect we have terminated the program. If a Head Start program loses funding for 60, 90, or more days, the program is likely to be so financially handicapped that the result could be the same as a termination of funding.

Response: We disagree that suspension is tantamount to termination. We only use suspension when such measure is allowed under the Act and usually in extraordinary circumstances. From 2013 to 2015, we issued 5 summary suspensions. Of the 5 summary suspensions, 4 resulted in termination.

Comment: Some commenters recommended we describe how programs should appeal findings to the HHS official.

Response: We did not prescribe how programs should appeal findings to the HHS official. There is no formal process for how programs must appeal findings to the HHS official. However, regardless of how evidence is presented to the HHS official, we will consider it.

Section 1304.5 Termination and Denial of Refunding

In this section describe the circumstances under which HHS can terminate, and, deny refunding or reduce funding. We also discuss appeal procedures for terminations and denials of refunding. We address the one comment we received on this section below.

Comment: Some commenters asked us to define "financial viability" again because our proposed definition was too broad and too subjective. A commenter proposed the following definition: "Financial viability means that an organization is able to meet its financial obligations as they become due."

Response: We did not revise our definition for "financial viability." However, we will clarify here what we mean by the phrase "balance funding and expenses." The phrase "balance funding and expenses" refers to the status of a grantee's funds and obligations by the end of the funding period. We understand throughout a funding period, funding and expenses will not always remain balanced. However, they should balance by the end of the funding period.

Section 1304.6 Appeal for Prospective Delegate Agencies

Section 646(a)(1) of the Act requires appeal procedures for certain conflicts between delegates and grantees. The Act requires a timely and expeditious appeal to the Secretary for an entity who wants to serve as a delegate and whose application has been rejected or not acted upon.

The previous regulation included an additional step that allowed prospective delegate agencies to appeal application decisions to the grantee first. This extra step added nothing to the application appeal process beyond extending it. Therefore, in the NPRM, we proposed to eliminate this extra step. We also proposed to eliminate the reconsideration process. We address the one comment we received on this section below.

Comment: According to one commenter, because we eliminated the appeal between prospective delegate agencies and grantees and require only the appeal to ACF, there may be occasions where a grantee wishes to reconsider its decision about a prospective delegate agency.

Response: Granted, there may be occasions where a grantee wishes to reconsider its decision about a delegate agency. We did not prohibit a grantee that chooses to reconsider its decision about a prospective delegate agency, but we did not require the grantee to do so either.

Section 1304.7 Legal Fees

This section focuses on grantees' right to attorneys and attorney fees. In the NPRM, we proposed to revise this section to align with section 646(a)(4)(C) of the Act, which requires the Secretary to prescribe procedures that prohibit a Head Start agency from using program grant funds to pay attorney fees and costs incurred during an appeal. This section also addresses when an agency may apply for reimbursement of fees and the procedures for doing so.

Comment: Some commenters asked us to clarify whether delegate agencies can seek reimbursement for legal fees.

Response: No. Delegate agencies cannot seek reimbursement for legal fees. The Act only speaks to the reimbursement of legal fees for the grantee appealing an HHS decision.

Designation Renewal; Subpart B

We did not make changes to the content of this subpart and therefore did not invite comments in the NPRM. We made technical changes to reorder what was part 1307, where this subpart was located in the previous rule, in a logical order for this rule. Although we did not invite comments, some commenters raised concerns about the Designation Renewal System and offered suggestions for alternate approaches. As prescribed by the Administrative Procedures Act, because we did not give notice of any potential changes we cannot make any changes in the final rule.

Selection of Grantees Through Competition; Subpart C

Section 641(d)(2) of the Act outlines the specific criteria the Secretary must use to select grantees and allow consideration of "other factors" and we refer to this citation in our regulatory text. This subpart revises previous program performance standards to reflect a more transparent and streamlined process for Head Start grant competitions and outline the other factors that are considered. We received comments on this section and discuss them below.

Comment: Commenters were concerned about removing the previous criteria for grantee selection regarding opportunities for employment and for the direct participation of parents in planning, conducting, and administering the program.

Response: In the Act, Congress included an extensive list of criteria that must be considered when selecting from among qualified applicants. This list includes family and community involvement, and thus by referencing section 641(d)(2) of the Act, these important concepts are covered by this section of the regulation. This list includes the important participation of families and communities.

Replacement of American Indian and Alaska Native Grantees; Subpart D

This subpart outlines the requirements for replacing American Indian and Alaska Native Head Start programs. We did not receive any comments on this section and did not make any changes.

Head Start Fellows Program, Subpart E

This subpart outlines the requirements for administration of the Head Start Fellows Program. We did not receive any comments on this section and did not make any changes.

Definitions; Part 1305

In this part, we include definitions from all sections of the previous rule for ease of grantee and prospective grantee understanding and transparency. In the previous rule, definitions were attached to each section. We consolidated definitions that were repeated in multiple sections in the previous rule. In addition, we removed many definitions that were either not meaningful or did not add to the widely understood meaning. We also removed definitions when it was clearer to incorporate their meaning into the provisions themselves or when the terms were not included in the final rule. We restored definitions from the previous rule that were not included in the NPRM when we used these terms in the final rule. We added some new definitions to this part in order to support other revisions throughout the rule or to provide technical clarity including their statutory basis in the Act, and reference the definitions in other relevant pieces of legislation where appropriate. Finally, we made a technical change to add a section on the purpose of this part, and renamed and redesignated the proposed section § 1305.1 to § 1305.2 in this final rule.

We received many comments on this part. Many commenters requested that we add additional definitions. Others asked that additional details be included in previous or proposed definitions. Others pointed out inconsistencies between definitions and asked for clarification. Finally, commenters asked that definitions from the Act and other statutes be spelled out in the rule. We discuss and respond to each of these categories of comments below.

Comment: Many commenters requested a definition for "planned operation."

Response: In light of the changes to the service duration requirements for center-based programs in § 1302.21(c) that remove the term "planned operation," we have deleted the definitions for "hours of operation" because they are no longer necessary. We added a definition for "hours of planned class operations."

Comment: Many commenters requested definitions that were not in the previous rule or the NPRM including: authorized caregiver, directory information, entry, high-quality pre-K, noncompliance, inclusion, LEA, frequently absent, unexcused absence, material, standardized and structured assessments, seclusion/restraint, and research-based.

Response: We did not include definitions for directory information, entry and seclusion/restraint because they are not used in the performance standards and so need no definition. We did not define frequently absent or unexcused absence to allow programs reasonable flexibility to define those terms to best meet the needs of the families they serve. We did not define authorized caregiver, LEA, noncompliance, material or inclusion because we are using their widely understood meaning. We did not define high-quality pre-K but changed the language in § 1302.14(a)(3) to include that pre-kindergarten must be comprehensive and available for a full school day. Similarly we did not define standardized and structured assessments but added in § 1302.33(b)(1) that they may observation-based or direct. We did not include a definition for deficiency because if it defined by the Act and we rely entirely on that statutory definition.

Comment: Many commenters asked that definitions from statutes, including the Head Start Act, IDEA, and McKinney-Vento, be restated as definitions in this rule.

Response: We did not define terms when we are relying on the definition from other statues.

Comment: Many commenters requested clarification of definitions that were in the previous rule or the NPRM, such as enrolled, family, and federal interest.

Response: We have modified the definition of enrolled to clarify that a child is not considered enrolled until they attend the program for center-based and family child care or received a home visit for home-based. We do not believe the definitions of family or federal interest needed changes.

Comment: Commenters pointed out that the definition of Migrant or Seasonal Head Start Program did not limit agricultural work to "the production and harvesting of tree and field crops," while the definition of migrant family did limit it in this way.

Response: We removed this phrase to make the definitions consistent.

Comment: Some commenters suggested adding language to the regulation stating that DLLs should be defined and identified in a consistent manner. Some also suggested including a definition for DLLs in the regulation.

Response: We do not agree that we should require programs to identify DLLs in a consistent manner in regulation, as this would unnecessarily limit program flexibility to develop their own processes for identifying DLLs. However, we do agree that it is important to incorporate a definition for "dual language learner" into regulation. We added a definition to part 1305 that is consistent with definitions used by experts in the field. This definition is inclusive of children who have a home language other than English, as well children who have home languages of both English and another non-English language.

VI. Regulatory Process Matters

a. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA),[123] as amended by the Small Business Regulatory Enforcement Fairness Act, requires federal agencies to determine, to the extent feasible, a rule's economic impact on small entities, explore regulatory options for reducing any significant economic impact on a substantial number of such entities, and explain their regulatory approach.

This final rule will not result in a significant economic impact on a substantial number of small entities. It is intended to ensure accountability for federal funds consistent with the purposes of the Improving Head Start for School Readiness Act of 2007[124] and is not duplicative of other requirements.

b. Regulatory Planning and Review Executive Order 12866

Executive Order 12866 requires federal agencies to submit significant regulatory actions to the Office of Management and Budget (OMB) for review. The Order defines "significant regulatory actions," generally, as any regulatory action that is likely to result in a rule that may (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.[125] This final rule is different from many rules in the federal government in that it will not require Head Start programs to spend more or less money on Head Start services, rather it will require programs to spend the money they are awarded in different ways. Nonetheless, given that the cost of the rule exceeds $100 million and that, if fully implemented, the costs will either be borne by the federal government in the form of additional appropriations for Head Start or by Head Start programs in the form of loss of slots for eligible children and teacher employment, we have determined this rule represents a significant regulatory action as defined by Executive Order 12866. Given both the directives of the Order and the importance of understanding the costs savings, and benefits associated with these requirements both with and without additional appropriations, we describe the costs, savings, and benefits associated with this final rule as well as available regulatory alternatives below.

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[123] 5 U.S.C. 605(b).

[124] 42 U.S.C. 9801

1. Need for Regulatory Action

The purpose of Head Start, as prescribed by the Act, is to "promote the school readiness of low-income children by enhancing their cognitive, social, and emotional development." [126] This mission is based upon decades of scientific research that documents the strong and lasting impact of children's experiences in their first five years of life on brain development, learning, and health,[127,128,129] and the significant economic impact of such benefits on children individually and on society as a whole. A wealth of research suggests that participation in early learning programs can help support optimal child development during these crucial first five years, particularly for children from low-income families, with benefits for society lasting well into adulthood.[130] [131] [132] [133] However, provision of consistently high-quality early learning experiences is central to reaping these benefits from early learning programs, including Head Start programs. The congressionally mandated, randomized control trial study of Head Start's impact did not show lasting effects on the outcomes measured beyond the end of the Head Start program years for all children. Specifically, while the Impact Study found effects at the end of participation in Head Start, by third grade the control and treatment groups showed no significant differences.[134] However, recent reanalysis of data from the Head Start Impact Study suggests that those programs that were full-day had a more positive impact on children's cognitive outcomes.[135] In order for Head Start to achieve its mission to be an effective tool in supporting children's success in kindergarten and beyond, all programs must be high quality. Decades of best practices, the latest research in early education, expert advice, the Secretary's Advisory Committee's recommendations, and Congressional mandates from the Act, all demonstrate that more can be done to ensure all Head Start programs provide consistently high-quality early learning experiences that prepare children for kindergarten and have long-term effects on their academic success. These findings all culminate in the need for policy changes. Additionally, we streamlined requirements and minimized administrative burden on local programs anticipate these changes will help move Head Start away from a compliance-oriented culture to an outcomes-focused one. Furthermore, we believe this approach will support better collaboration with other programs and funding streams. We believe the final rule, which incorporates these needed changes, will empower all programs to achieve this goal.

2. Cost and Savings Analysis

In this section, we first summarize and respond to comments we received on the Regulatory Impact Analysis in the NPRM. Then, we describe the data sources and general methodology used to calculate costs and savings throughout this analysis. We also summarize the total estimated costs and cost savings associated with this rule, split into four categories: costs and cost savings borne by Head Start, costs and cost savings borne by other parties, opportunity costs, and transfer costs. Finally, we itemize the cost and cost savings estimates associated with individual provisions and describe the assumptions, methodology, and data used to calculate each estimate.

Comment and Response

Comment: Many commenters noted that new requirements would impose additional costs. Some of the costs that commenters highlighted were already accounted for in the Regulatory Impact Analyses of the NPRM including costs associated with increased duration, background checks, curriculum requirements, mentor coaching, additional staff qualifications, the waiver application process, providing annual notice to parents of release of personally identifiable information, and costs to implement the changes to the Head Start Program Performance Standards (HSPPS). Other commenters explicitly suggested that the Regulatory Impact Analysis underestimated the costs associated with the provisions it addressed, such as the cost of additional facilities or other start-up including cots for naptime, in the estimate for increasing Head Start center-based duration. Some of these commenters did not provide evidence or a rationale to support these claims. Other commenters suggested costs in their community would be higher for a variety of reasons.

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[125] Executive Order 12866 section 3(f)(1).

[126] 42 U.S.C. 9831

[127] National Scientific Council on the Developing Child (2007). *The Timing and Quality of Early Experiences Combine to Shape Brain Architecture: Working Paper No. 5.* Cambridge, MA: Author.

[128] Anda R.F., Felitti V.J., Bremner J.D., Walker J.D., Whitfield C., Perry, B.D., Dube, S.R., & Giles, W.H. (2006). The enduring effects of abuse and related adverse experiences in childhood. A convergence of evidence from neurobiology and epidemiology. *European Archives of Psychiatry and Clinical Neuroscience, 256(3),* 174–186.

[129] National Scientific Council on the Developing Child (2010). *Early Experiences Can Alter Gene Expression and Affect Long-Term Development: Working Paper No. 10.* Cambridge, MA: Author.

[130] Heckman, J.J., Moon, S.H., Pinto, R., Savalyev, P.A. & Yavitz, A. (2010). The Rate of Return to the High/Scope Perry Preschool Program. Journal of Public Economics, 94(1–2), 114–128.

[131] The Council of Economic Advisers. (December, 2014). *The Economics of Early Childhood Investments.* Washington, DC: Authors.

[132] Reynolds, A.J., Temple, J.A., Robertson, D.L., Mann, E.A. (2002). Age 21 Cost-Benefit Analysis of the Title I Chicago Child-Parent Centers. *Educational Evaluation and Policy Analysis,* 24(4), 267–303.

[133] Yoshikawa, H., Weiland, C., Brooks-Gunn, J., Burchinal, M., . . .Zaslow, M. (2013). Investing in our future: The evidence base on preschool education. Foundation for Child Development.

[134] Puma, M., Bell, S., Cook, R., Heid, C., Broene, P., Jenkins, F., & Downer, J. (2012). Third grade follow-up to the Head Start impact study final report. *US Department of Health and Human Services Office of Planning, Research and Evaluation.*

[135] Walters, C. (2014). *Inputs in the production of early childhood human capital: Evidence from Head Start.* American Economic Journal: Applied Economics, 7(4), 76–102.

Response: We estimate the costs associated with increasing duration, additional background checks, new curriculum requirements, coaching, additional staff qualifications, the waiver application process, providing annual notice to parents of release of personally identifiable information, and many other new requirements in the HSPPS in this Regulatory Impact Analysis. We acknowledge there are additional costs associated with facilities and other start-up activities for increasing duration Given the period of ramp-up that most programs will need to implement the duration requirements with additional funding, we anticipate that a portion of any first 12-month operational award will be available for the purchase or renovation of facilities and other start-up activities before programs begin serving children at the higher duration. Nonetheless, we have included an estimate of start-up costs and assumed that these one-time costs will be borne the year prior to the effective dates for duration requirements to reflect the additional costs that would be incurred if these requirements were implemented without adequate funding. In addition, we have adjusted estimates throughout this analysis to reflect revisions to requirements in response to public comments, for example, the final rule requires 1,020 annual hours rather than prescribing 6 hours per day and 180 days per year for Head Start center-based programs, and the final rule reinstates the requirement for parent committees. While we understand that costs of specific provisions will vary across communities, we use the best available data to estimate the cost for all Head Start programs, on average.

Comment: Some commenters expressed concerns related to costs that the NPRM would have imposed or they perceived the NPRM to impose. These costs include the cost of group socialization sites needing to be licensed, costs in rural areas if the home-based option for preschool was removed as a standard option, reduced benefits from the elimination of family partnership agreements, transportation for child health services, partnering with universities to adapt curricula, decreased in-kind matches in volunteer hours and engagement due to reduced enrollment, loss of transportation when partnering with an LEA because of full day requirements, and services to children with significant delays who do not yet have IEPs or IFSPs.

Response: Throughout the preamble of the final rule, we address comments suggesting concerns related to requirements that would have imposed unnecessary or unaccounted for costs. We revised the final rule to provide greater flexibility or prevent unintended consequences that would have resulted in additional costs for many of the concerns commenters noted. For example, the final rule requires 1,020 annual hours rather than prescribing 6 hours per day and 180 days per year for Head Start center-based programs. The final rule also allows programs to align their schedules with their local education agency to maintain or facilitate partnerships. These changes address concerns about costs that would arise from disrupted partnerships with local education agencies and costs associated with extending the year in cases where 1,020 annual hours are already being provided through a slightly shorter year.

Comment: Some commenters expressed concerns about costs that are implicitly required in current regulation but more explicitly required in the revision of the HSPPS including tracking and analyzing data for continuous quality improvement, providing mental health consultation services, and appropriate training for staff or volunteers involved in the transportation of children.

Response: Although we recognize there are costs associated with these services, the purpose of the Regulatory Impact Analysis is to estimate the costs associated with new requirements. Tracking and analyzing data for continuous quality improvement, providing mental health consultation services, and appropriate training for staff or volunteers are requirements that existed in the previous performance standards so those costs have not been quantified here. However, in the Benefits Analysis section, we have noted that the clarity the final rule provides should lead to improved compliance with these and other requirements which should be associated with improved child safety and stronger child and family outcomes.

Comment: Some commenters suggested that the Regulatory Impact Analysis should incorporate costs associated with prioritizing three year olds for enrollment in Head Start. These commenters highlighted the lower group size and ratio requirements for three-year-olds as an indication of greater cost.

Response: We would consider prioritizing three-year olds and thereby serving fewer children in Head Start a conversion that would not change the grantee's overall budget and would not be supported by additional funds. Therefore we have not accounted for any monetary costs associated with this provision here. While we recognize that this would lead to a reduction in slots, it would actually be an increase in the number of children served by early childhood programs overall, because the prioritization is only required if there are programs in the community serving four-year olds. Further, we lack data to support a reasonable assumption about how often and at what point in the future other programs in Head Start communities would be available to serve four-year-olds. Therefore, we have not quantified these costs to programs or any transfer of benefits here.

Comment: Many commenters suggested specific costs associated with new requirements in the NPRM that are being maintained in the final rule and that were not addressed in the original Regulatory Impact Analysis, including use of a parenting curriculum, attempting to contact parents if they have not notified the program that their children will be absent, participation in state Quality Improvement Rating Systems, and participation in state longitudinal data systems.

Response: We have estimated costs associated with these requirements in the Regulatory Impact Analysis below.

Comment: Many commenters expressed the desire for the Head Start Performance Standards to require and account for increased teacher compensation.

Response: We agree that teacher compensation is vitally important to attracting and retaining effective teachers. However, addressing compensation is outside the scope of this regulation because teacher compensation is determined by congressional appropriations and local decisions. Nonetheless, our cost estimates for increasing duration assume costs will be driven in large part by additional pay for teacher's time, such that programs that must increase their duration as a result of this rule could increase teacher pay in a commensurate fashion if sufficient funds are available.

Comment: Some commenters suggested the Regulatory Impact Analysis should include mention of the benefits associated with longer duration allowing parents to work.

Response: We agree and have revised the discussion of potential benefits to include the benefits associated with allowing more Head Start parents to work.

Comment: Some commenters suggested revisions to our cost estimates for specific provisions. Commenters suggested we revise the assumption that there would be no additional administrative costs associated with transforming double session programs into single session, full school day and full school year programs. Commenters also suggested that the regulatory impact analysis should build in cost of living increases overtime to reflect the true cost of the rule.

Response: We have revised our estimates in response to these comments. With regard to administrative costs we no longer assume a reduction in the cost estimate for increasing duration based on lower administrative costs. In addition, while the Regulatory Impact Analysis reports costs in real dollars, we have added a table in the section on the implications of Congressional and Secretarial action that reflects the costs of the rule, adjusted for cost of living increases over time, to ensure the full cost and the potential slot loss associated with those costs are clearly articulated.

Data Sources and Methodology

The majority of the estimates in this regulatory impact analysis utilize two Office of Head Start internal datasets: The Grant Application and Budget Instrument (GABI) and the Program Information Report (PIR). Whenever possible, in this regulatory impact analysis, estimates are based upon these datasets. When a data point is necessary to estimate the cost of any provision that cannot be drawn from the GABI or PIR, other data sources are utilized. These data sources are described or cited in the narrative of the relevant cost estimates.

The Head Start GABI is a uniform OMB approved application and budget instrument to standardize the format for the collection of program-specific data grantees provide with a continuation grant application. Head Start grantees provide a range of data on their proposed budgets including non-federal share, any other sources of funding, program options, and program schedules.

The PIR is a survey of all grantees that provides comprehensive data on Head Start, Early Head Start and Migrant Head Start programs nationwide. Data collection for the PIR is automated to improve efficiency in the collection and analysis of data. Head Start achieves a 100 percent response rate annually from approximately 2,600 respondents.

These datasets have some limitations. For example, depending on where programs are in the application process or if they are submitting competitive applications, rather than continuation applications, the GABI data can be incomplete. We addressed this limitation in two ways. For grantees that had not submitted GABI data in FY 2015 due to DRS transitions or other factors, we used their FY 2014 GABI data. In addition, to account for missing data, we determined which specific grantees did not have program schedules in the 2015 GABI data, and then determined the funded enrollment associated with those specific grantees using data from the Head Start Enterprise System. Through this analysis, we learned that 11 percent of Head Start funded enrollment slots and 13 percent of Early Head Start enrollment slots are missing from the 2015 GABI data. Therefore, throughout this analysis, we increase estimates using GABI data by 11 percent for Head Start and 13 percent for Early Head Start. Further, the PIR data is self-reported data that has not been independently verified.

The methodology we use to estimate costs and cost savings associated with individual provisions varies throughout this analysis. We have included a description of each methodology in the Itemized Costs and Cost Savings section of this analysis. As appropriate, estimates associated with new salaries have been doubled to account for fringe benefits and overhead. Estimates associated with duration requirements that increase the hours and days staff must work and increases to salaries based on higher credentials are inflated by one-third to include costs associated with an increase in fringe benefits but exclude any additional overhead costs.

Finally, in general, we have rounded total cost estimates but have not rounded itemized cost estimates for transparency of the estimation process. These unrounded itemized cost estimates should not be interpreted as overly precise, but instead represent our best estimation given limitations.

Summary of Costs and Cost Savings

Throughout this analysis, we identify and itemize the costs and cost savings to society associated with the changes from the previous regulation in three categories: costs borne by Head Start, costs borne by other parties, and opportunity costs. We describe the calculation of each of these costs in the appropriate sections throughout this analysis. The table below summarizes all of the itemized costs for every year over a ten year window. The final year (year ten) represents our best estimation of costs in year ten and ongoing costs thereafter. We analyze the costs of the regulation two ways in the table and throughout this analysis—we estimate the costs of the regulation without consideration of the substantial resources provided in FY 2016 to increase duration in Head Start and we estimate the costs net of these resources which have already been provided and are now part of the budget baseline for the Head Start program, assuming this funding increase is maintained across the ten year window. In year 10, the total cost to Head Start after accounting for the funding Congress has already provided to expand duration total $1,003,152,645; without the $294 million in funding provided in FY 2016 and now part of the budget baseline, the total cost would be $1,297,152,645. In year ten and ongoing, costs borne by other parties total $46,464,140, and opportunity costs total $4,202,017. Therefore, we estimate the net cost to society of the final rule, if fully implemented, to be $1,053,818,802 in year ten and ongoing, when the funding Congress has already provided is taken into account.

Without additional appropriations in future years or action by the Secretary as described in § 1302.21(c)(3) to lower the requirements described in paragraphs § 1302.21(c)(2)(iii) and (iv) of the final rule, Head Start programs would need to absorb any additional costs within their current budgets. We discuss the implications of Congressional and Secretarial actions, as well as potential slot and teacher job loss, in more detail in the Benefits Analysis section below.

SUMMARY TABLE OF ALL COSTS BORNE BY HEAD START YEARS 1–5

	Year 1 2016–2017 *	Year 2 2017–2018 *	Year 3 2018–2019 *	Year 4 2019–2020 *	Year 5 2020–2021 *
Increased Head Start Center-Based (CB) Program Duration, Excluding Duration Funding Appropriated in FY 2016				$508,440,805	$508,440,805
FY 2016 Funding Appropriated to Expand Head Start CB Duration				(263,121,940)	(263,121,940)
Net Cost of Head Start CB Duration Increase				245,318,865	245,318,865

SUMMARY TABLE OF ALL COSTS BORNE BY HEAD START YEARS 1–5—Continued

	Year 1 2016–2017 *	Year 2 2017–2018 *	Year 3 2018–2019 *	Year 4 2019–2020 *	Year 5 2020–2021 *
Increased EHS CB Duration, Excluding Duration Funding Appropriated in FY 2016	....	....	$30,878,060	30,878,060	30,878,060
FY 2016 Funding Appropriated to Expand EHS CB Duration	....	....	(30,878,060)	(30,878,060)	(30,878,060)
Net Cost of EHS CB Duration Increase	....	....	0	0	0
Start-up Costs for Duration Increase for CB Programs	....	$6,175,612	101,688,161	....	124,109,936
Increased EHS Home-Based (HB) Duration	....	8,188,508	8,188,508	8,188,508	8,188,508
Waiver for Two-Year-Old Ratios	$(24,541,262)	(24,541,262)	(24,541,262)	(24,541,262)	(24,541,262)
Waiver Applications	42,751	54,137	60,153	80,899	80,899
Home Visit for Frequently Absent Children	927,603	834,842	742,082	649,322	556,562
Parent Contact—Unexpectedly Absent Children	3,540,199	3,540,199	3,540,199	3,540,199	3,540,199
Associate's Degree for Head Start (HS) Teachers	10,472,585	10,472,585	10,472,585	10,472,585	10,472,585
Home-visiting CDA for Home Visitors	....	....	5,112,499	5,112,499	5,112,499
Credential for New Family Service Workers	549,046	549,046	549,046	549,046	549,046
Bachelor's Degree for New Management Staff	2,182,809	3,977,108	5,515,809	6,798,912	7,826,417
Mentor Coaching	....	141,978,651	141,978,651	141,978,651	141,978,651
Improving Curriculum	....	4,390,220	4,390,220	4,390,220	4,390,220
Monitoring Fidelity of Curriculum Implementation	....	33,983	33,983	33,983	33,983
Assessments for Dual Language Learners	....	6,082,338	6,082,338	6,082,338	6,082,338
Removal of Head Start-specific IEPs	(41,180,576)	(41,180,576)	(41,180,576)	(41,180,576)	(41,180,576)
Parenting Curriculum	4,055,157	4,055,157	4,055,157	4,055,157	4,055,157
Memorandum of Understanding (MOU)	61,506	....	....	....	....
Criminal Background Checks	....	4,117,348	4,117,348	4,117,348	4,117,348
Mediation and Arbitration	333,000	333,000	333,000	333,000	333,000
Removal of Annual Audits	(306,000)	(306,000)	(306,000)	(306,000)	(306,000)
Delegate Appeals	(833,638)	(833,638)	(833,638)	(833,638)	(833,638)
Clarification of Facilities Application Process	(4,350,000)	(4,350,000)	(4,350,000)	(4,350,000)	(4,350,000)
Community Assessment	(1,152,558)	(1,152,558)	(1,152,558)	(1,152,558)	(1,152,558)
Managerial Planning	(2,298,905)	(2,298,905)	(2,298,905)	(2,298,905)	(2,298,905)
Data Management	....	6,643,811	6,643,811	6,643,811	6,643,811
Participation in QRIS	....	1,695,928	1,695,928	1,695,928	1,695,928
Participation in State longitudinal data systems	....	824,593	824,593	824,593	824,593
Implementation Planning	3,474,474	3,474,474	....	....	....
Total, *Excluding* Duration Funding Appropriated in FY 2016	(46,320,371)	134,637,446	264,118,036	672,906,362	797,951,042
Total, *Including* Duration Funding Appropriated in FY 2016	n/a	n/a	n/a	378,906,362	503,951,042

* Year ranges refer Head Start program years, which for these estimates, begin on August 1st of each year and end on or before July 31st.

SUMMARY TABLE OF ALL COSTS YEARS 6–10

	Year 6 2021–2022 *	Year 7 2022–2023 *	Year 8 2023–2024 *	Year 9 2024–2025 *	Year 10 2025–2026 *
Increased Head Start CB Program Duration, Excluding Duration Funding Appropriated in FY 2016	$1,128,990,485	$1,128,990,485	$1,128,990,485	$1,128,990,485	$1,128,990,485
FY 2016 Funding Appropriated to Expand Head Start CB Duration	(263,121,940)	(263,121,940)	(263,121,940)	(263,121,940)	(263,121,940)
Net Cost of Head Start CB Duration Increase	865,868,545	865,868,545	865,868,545	865,868,545	865,868,545
Increased EHS CB Program Duration, Excluding Duration Funding Appropriated in FY 2016	30,878,060	30,878,060	30,878,060	30,878,060	30,878,060
FY 2016 Funding Appropriated to Expand EHS CB Duration	(30,878,060)	(30,878,060)	(30,878,060)	(30,878,060)	(30,878,060)
Net Cost of EHS CB Duration Increase	0	0	0	0	0
Increased EHS HB Duration	8,188,508	8,188,508	8,188,508	8,188,508	8,188,508
Waiver for Two-Year-Old Ratios	(24,541,262)	(24,541,262)	(24,541,262)	(24,541,262)	(24,541,262)
Waiver Applications	104,650	20,930	20,930	20,930	20,930
Home Visit for Frequently Absent Children	463,801	463,801	463,801	463,801	463,801
Parent Contact—Unexpectedly Absent Children	3,540,199	3,540,199	3,540,199	3,540,199	3,540,199
Associate's Degree for HS Teachers	10,472,585	10,472,585	10,472,585	10,472,585	10,472,585

Summary Table of All Costs Years 6–10—Continued

	Year 6 2021–2022 *	Year 7 2022–2023 *	Year 8 2023–2024 *	Year 9 2024–2025 *	Year 10 2025–2026 *
Home-visiting CDA for Home Visitors	5,112,499	5,112,499	5,112,499	5,112,499	5,112,499
Credential for New Family Service Workers	549,046	549,046	549,046	549,046	549,046
Bachelor's Degree for New Management Staff	8,726,123	9,370,230	10,014,338	10,525,534	10,908,931
Mentor Coaching	141,978,651	141,978,651	141,978,651	141,978,651	141,978,651
Improving Curriculum	4,390,220	4,390,220	4,390,220	4,390,220	4,390,220
Monitoring Fidelity of Curriculum Implementation	33,983	33,983	33,983	33,983	33,983
Assessments for Dual Language Learners	6,082,338	6,082,338	6,082,338	6,082,338	6,082,338
Removal of Head Start-specific IEPs	(41,180,576)	(41,180,576)	(41,180,576)	(41,180,576)	(41,180,576)
Parenting Curriculum	4,055,157	4,055,157	4,055,157	4,055,157	4,055,157
Memorandum of Understanding (MOU)	....	....	....	....	....
Criminal Background Checks	4,117,348	4,117,348	4,117,348	4,117,348	4,117,348
Mediation and Arbitration	333,000	333,000	333,000	333,000	333,000
Removal of Annual Audits	(306,000)	(306,000)	(306,000)	(306,000)	(306,000)
Delegate Appeals	(833,638)	(833,638)	(833,638)	(833,638)	(833,638)
Clarification of Facilities Application Process	(4,350,000)	(4,350,000)	(4,350,000)	(4,350,000)	(4,350,000)
Community Assessment	(1,152,558)	(1,152,558)	(1,152,558)	(1,152,558)	(1,152,558)
Managerial Planning	(2,298,905)	(2,298,905)	(2,298,905)	(2,298,905)	(2,298,905)
Data Management	6,643,811	6,643,811	6,643,811	6,643,811	6,643,811
Participation in QRIS	1,695,928	2,024,583	2,024,583	2,024,583	2,352,595
Participation in State longitudinal data systems	824,593	965,550	965,550	965,550	1,106,507
Implementation Planning	....	....	....	....	....
Total, *Excluding* Duration Funding Appropriated in FY 2016	1,294,396,889	1,295,285,932	1,296,895,589	1,297,406,786	1,297,152,645
Total, *Including* Duration Funding Appropriated in FY 2016	1,000,396,889	1,001,285,932	1,002,895,589	1,003,406,786	1,003,152,645

* Year ranges refer Head Start program years, which for these estimates, begin on August 1st of each year and end on or before July 31st.

Summary Table of All Costs Borne by Other Parties and Opportunity Costs Years 1–5

	Year 1 2016–2017 *	Year 2 2017–2018 *	Year 3 2018–2019 *	Year 4 2019–2020 *	Year 5 2020–2021 *
Costs Borne by Other Parties					
Managerial Planning	$(1,043,016)	$(1,043,016)	$(1,043,016)	$(1,043,016)	$(1,043,016)
Data Management	....	741,978	741,978	741,978	741,978
Memorandum of Understanding (MOU)	28,679	....	....	....	....
Community Assessment	(352,028)	(352,028)	(352,028)	(352,028)	(352,028)
Improving Curriculum	....	140,396	140,396	140,396	140,396
Implementation Planning	1,624,843	1,624,843	....	....	....
Waiver Application	14,023	17,758	19,731	26,537	26,537
Bachelor's Degree for New Management Staff	1,036,673	1,888,833	2,619,603	3,228,982	3,716,971
Participation in QRIS	....	888,598	888,598	888,598	888,598
Participation in State longitudinal data systems	....	399,268	399,268	399,268	399,268
Removal of Head Start-specific IEPs	41,180,576	41,180,576	41,180,576	41,180,576	41,180,576
Subtotal	42,489,751	44,745,228	43,853,127	44,469,312	44,957,301
Opportunity Costs					
Home Visit for Frequently Absent Children	455,721	410,149	364,577	319,005	273,433
Criminal Background Checks	....	838,985	838,985	838,985	838,985
Data Management	....	2,393,194	2,393,194	2,393,194	2,393,194
Subtotal	455,721	4,384,306	4,338,734	4,293,161	4,247,589

* Year ranges refer Head Start program years, which for these estimates, begin on August 1st of each year and end on or before July 31st.

Summary Table of All Costs Borne by Other Parties and Opportunity Costs Years 6–10

	Year 6 2021–2022 *	Year 7 2022–2023 *	Year 8 2023–2024 *	Year 9 2024–2025 *	Year 10 2025–2026 *
Costs Borne by Other Parties					
Managerial Planning	$(1,043,016)	$(1,043,016)	$(1,043,016)	$(1,043,016)	$(1,043,016)

SUMMARY TABLE OF ALL COSTS BORNE BY OTHER PARTIES AND OPPORTUNITY COSTS YEARS 6–10—Continued

	Year 6 2021–2022*	Year 7 2022–2023*	Year 8 2023–2024*	Year 9 2024–2025*	Year 10 2025–2026*
Data Management		741,978	741,978	741,978	741,978
Memorandum of Understanding (MOU)					
Community Assessment	(352,028)	(352,028)	(352,028)	(352,028)	(352,028)
Improving Curriculum	140,396	140,396	140,396	140,396	140,396
Implementation Planning					
Waiver Application	34,327	6,865	6,865	6,865	6,865
Bachelor's Degree for New Management Staff	4,144,265	4,450,168	4,756,072	4,998,852	5,180,938
Participation in QRIS	888,598	1,119,660	1,119,660	1,119,660	1,350,409
Participation in State longitudinal data systems	399,268	469,767	469,767	469,767	540,267
Removal of Head Start-specific IEPs	41,180,576	41,180,576	41,180,576	41,180,576	41,180,576
Subtotal	45,392,386	45,972,388	46,278,292	46,521,072	46,464,140
Opportunity Costs					
Home Visit for Frequently Absent Children	227,861	227,861	227,861	227,861	227,861
Criminal Background Checks	838,985	838,985	838,985	838,985	838,985
Data Management	2,393,194	2,393,194	2,393,194	2,393,194	2,393,194
Subtotal	4,207,017	4,202,017	4,202,017	4,202,017	4,202,017

* Year ranges refer Head Start program years, which for these estimates, begin on August 1st of each year and end on or before July 31st.

SUMMARY TABLE OF NET COST TO SOCIETY YEARS 1–10

	Year 1 2016–2017*	Year 2 2017–2018*	Year 3 2018–2019*	Year 4 2019–2020*	Year 5 2020–2021*
Net Cost to Society, Excluding Duration Funding Appropriated Beginning in FY 2016	$(3,374,899)	$183,367,712	$311,910,629	$721,269,567	$846,756,665
Net Cost to Society, Including Duration Funding Appropriated Beginning in FY 2016	n/a	n/a	n/a	427,269,567	552,756,665
	Year 6 2021–2022*	**Year 7 2022–2023***	**Year 8 2023–2024***	**Year 9 2024–2025***	**Year 10 2025–2026***
Net Cost to Society, Excluding Duration Funding Appropriated Beginning in FY 2016	$1,343,592,024	$1,344,990,571	$1,346,906,131	$1,347,660,108	$1,347,818,802
Net Cost to Society, Including Duration Funding Appropriated Beginning in FY 2016	1,049,592,024	1,050,990,571	1,052,906,131	1,053,660,108	1,053,818,802

* Year ranges refer Head Start program years, which for these estimates, begin on August 1st of each year and end on or before July 31st.

Itemized Costs and Cost Savings

In the following sections, we itemize each of the regulatory changes for which we expect there to be associated costs or cost savings in the areas of structural program option provisions, staff quality provisions, curriculum and assessment provisions, and administrative/managerial provisions.

Structural Program Option Provisions

This final rule includes several provisions that increase the duration of the Head Start experience for children. It also includes provisions intended to improve child attendance. We analyzed costs associated with the following specific requirements: minimum of 1,020 hours of planned class operations for all Head Start center-based programs in § 1302.21(c)(2)(iii)–(iv) minimum of 1,380 hours for all Early Head Start center-based programs in § 1302.21(c)(1)(i)–(ii); minimum of 46 home visits and 22 group socializations for all Early Head Start home-based programs in § 1302.22(c)(1)(i) and (ii); and additional home visits for chronically absent children, as appropriate, and contacting parents when children are unexpectedly absent in § 1302.16. In all cases, costs are estimated based on data about whether programs are currently meeting these new minimum requirements.

Increased Head Start Center-Based Program Duration

This final rule increases the minimum annual hours that Head Start programs must provide to 1,020 annual hours. The requirements in § 1302.21(c)(2)(iii) and (iv) phase in the minimum annual hour requirement for Head Start such that each grantee must operate 50 percent of its Head Start center-based slots at the 1,020 annual hour minimum by August 1, 2019 and 100 percent of its Head Start center-based slots at this minimum by August 1, 2021. Further, to minimize the potential for slot loss as described above the requirements in § 1302.21(c)(3) give the Secretary the authority to reduce these percentages if adequate funding is not available to support the policy.

These changes will increase the amount of exposure to Head Start experiences, which research suggests will, in turn, result in larger impacts on school readiness and long-term outcomes.[136] [137] Research suggests that previous Head Start minimums are inadequate to achieve strong child outcomes and effectively promote school readiness. Specifically, research on full school day programs, instructional time, summer learning loss and attendance demonstrates the importance of extending the minimum hours of early learning in Head Start.[138] [139] [140] [141] [142] [143] [144] [145] [146] [147] [148] [149] [150] [151] [152] [153] Research finds that pre-kindergarten programs that focus on intentional teaching and both small group and one-to-one interactions have larger impacts on child outcomes.

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50 Percent Estimate for the Extension of Head Start Center-Based Program Duration

Starting in year four following publication of this rule (program year 2019–2020), programs are required to serve 50 percent of their children in Head Start center-based classrooms for at least 1,020 hours per year. In this section, we estimate costs associated with the additional service provided by these programs. Note that Migrant and Seasonal Head Start programs are excluded from these requirements. We first estimate the marginal cost per child for the Head Start services that exist today, updated to account for teacher salary increases associated with the final rule. These salary increases are discussed later in this analysis. To estimate this cost, we first calculate the Head Start cost per child under the final rule by adding total Head Start grant expenditures in FY 2015 ($6,354,595,188) to teacher salary increases associated with requirements in the final rule in § 1302.91(e) ($7,874,124), and divide this sum by FY 2015 Head Start funded enrollment (791,886). This results in a cost per child of $8,035, which is an increase of ten dollars per child from the FY 2015 actual annual Head Start cost per child of $8,025.

We estimate costs for Head Start center-based double session and non-double session programs separately. We assume grantees will move double session and non-double sessions, and three-year-old and four- and five-year-old slots, to 1,020 annual hours proportionately.

Given that double session programs include a morning and afternoon session with the same teacher, we estimate that for every two children in these programs, the marginal cost of providing additional service in line with the rule's requirements will be equivalent to providing Head Start services to an additional child, resulting in a cost of $8,035. Therefore, we estimate for Head Start double session center-based programs, 31,197 new slots would need to be created and we estimate the cost to move these slots to 1,020 hours to be $250,664,993. However, this cost excludes the impact of the funding already provided by Congress in FY 2016 to expand duration. As discussed below, some of these costs will be covered by that funding.

We take a different approach to estimate costs for non-double session programs. We calculate the number of Head Start center-based non-double session slots that operate for fewer than 1,020 annual hours and would need to be increased in order for each grantee to meet the 50 percent requirement (121,116, after inflating values for missing GABI data). Based on GABI data, the average number of hours that a non-double session slot would need to add in order to reach the 1,020 hours annually is 290.354 hours. We assume that programs would choose to increase their service duration to the 1,020 annual hour requirement in a variety of ways, some by adding hours to each day of service and some by adding additional service days. Based on the service duration patterns of programs that currently provide 1,020 or more annual hours of service, we assume 30 percent of programs would decide to add only hours to each day of service already provided, and therefore their costs would be driven entirely by teaching salaries. We assume 70 percent of programs would choose to increase the number of days they operate per year to meet the 1,020 annual hour requirement.

We next estimate the marginal cost per hour per child for Head Start non-double session, center-based slots. This is done using the sum of the average teacher ($18.70) and average assistant teacher ($11.99) hourly wages from the PIR to calculate the cost per classroom per hour for teaching staff on average ($30.69). Then, we increased this cost per classroom per hour for teaching staff by 0.124 percent to account for the marginal increase in teacher salaries associated with all teaching staff meeting the minimum education requirements described later in this analysis ($7,874,124). This increase was calculated by finding the marginal increase in the cost per child after accounting for these salary increases ($8,035) from the FY 2015 actual cost per child for Head Start ($8,025). The new cost per classroom per hour for teaching staff is $30.73, on average. Then, we inflated this cost per classroom per hour by one-third to account for fringe benefits, which is $40.87 (we assumed no additional costs for overhead). We then assume that children will be served in classroom settings with the maximum allowable group size. To calculate the marginal cost per hour, we divide the hourly wage by the maximum group size for three-year olds (17) and four- and five-year-olds (20) to get an average marginal cost per hour per child for three-year olds ($2.40) and four- and five-year olds ($2.04).

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We then use FY 2015 PIR data to calculate the percentage of three-year-olds (42 percent) and four- and five-year-olds (58 percent) served by Head Start center-based programs. To calculate the cost of increasing the proportion of slots at 1,020 hours to 50 percent in each grantee by adding only hours to the day, we take 30 percent of the share of three-year-olds (42 percent) and four- and five-year-olds (58 percent) enrolled in these programs respectively to find the number of three-year-old slots (15,179) and four- and five-year-old slots (21,156) that would need additional hours to meet the requirement. We then calculate the average number of annual hours that non-double session Head Start center-based slots not currently meeting 1,020 annual hours would need to add to reach 1,020 hours, which is 290.354 hours. Finally, we multiply the estimated number of three-year-old slots (15,179) and four- and five-year-old slots (21,156) by their respective average marginal cost per hour per child ($2.40 and $2.04) and by the average number of hours these slots would need to increase to reach 1,020 annual hours (290.354) to get a total estimated cost for this 30 percent of non-double session slots of $23,108,599. However, this cost excludes the impact of the funding already provided by Congress in FY 2016 to expand duration. As discussed below, some of these costs will be covered by that funding.

As discussed above, we anticipate a different marginal cost per hour per child for the 70 percent of Head Start non-double session slots we assume will meet the 1,020 annual hours by adding days, because it would be necessary to extend all of the relevant child and family services for a longer program year in addition to the cost per classroom for teaching staff. In order to estimate these costs, we divide the average annual Head Start cost per child inflated for teacher salary increases as called for in § 1302.91(e) ($8,035) by the average number of hours per year provided across all Head Start center-based slots (956.49 hours) to get an average cost per hour of $8.40 to extend days. Then, to account for fringe benefits, we inflated 80% of this cost per hour by one-third (we assume no additional costs for overhead) because most programs spend approximately 80% of their budget on personnel. This results in an average cost per hour of $10.62 to extend days. We then multiplied the average number of hours these slots would need to increase to reach 1,020 annual hours (290.354) by the marginal cost per hour per child ($10.62), and by the number of slots that we estimated would meet 1,020 annual hours by adding days (84,781) to get an estimated cost of $261,427,256. Finally, we estimate the total cost for all Head Start non-double session center-based slots to meet the 50 percent requirement, using these two approaches, is $284,535,855. However, this cost excludes the impact of the funding already provided by Congress in FY 2016 to expand duration. As discussed below, some of these costs will be covered by that funding.

In sum, the total cost for Head Start double session and non-double session center-based slots to meet the 50 percent requirement is $535,200,848 before accounting for the $294 million in funding Congress has provided in FY 2016 to expand duration. However, because we assume that 5 percent of all programs currently not meeting the 1,020 for 50 percent of their slots will receive a waiver to continue operating at their current level of annual hours, we reduce this estimate by 5 percent for a total cost borne by Head Start of $508,440,805 before accounting for the $294 million in funding Congress has provided in FY 2016 to expand duration. These costs will be realized in years four and five, if the rule is fully implemented. As noted, Congress appropriated $294 million in FY 2016 to increase the duration of Early Head Start and Head Start programs. Thus, a substantial share of the $508 million in costs will be absorbed by this funding, assuming this funding increase is maintained across the ten year window.

50% EXTENSION OF HEAD START CENTER-BASED DURATION: COSTS BORNE BY HEAD START

	Total DS slots	New slots needed	Cost per child (less admin)	Cost
Double Session (DS)	62,393	31,197	$8,035	$250,664,993
	Slots	Average cost per child per hour	Hours needed	Cost
Non-double session adding hours (30%) 3 year olds	15,179	$2.40	290.354	$10,577,515
Non-double session adding hours (30%) 4 year olds	21,156	2.04	290.354	12,531,084
Subtotal				23,108,599
Non-double session adding days (70%)	84,781	10.62	290.354	261,427,256
Total, *Excluding* Duration Funding Appropriated Beginning in FY 2016				535,200,848
Less 5% Waiver, *Excluding* Duration Funding Appropriated Beginning in FY 2016				508,440,805
Total, *Including Duration* Funding Appropriated Beginning in FY 2016				245,318,865

100 Percent Estimate for the Extension of Head Start Center-Based Program Duration

Starting in year six following publication of the final rule (program year 2021–2022), most programs are required to serve children for at least 1,020 hours. In order to estimate the cost associated with this requirement for each grantee to operate all of their Head Start center-based slots for 1,020 annual hours, we used the same approach described above for the 50 percent requirement. The only difference in the estimate is that we used GABI data to calculate the number of slots for which each grantee would need to increase duration in order to operate all of its center-based Head Start slots for 1,020 annual hours. As above, we estimate the cost of increasing double session and non-double session slots to 1,020 annual hours separately. Therefore, as described above, we estimate for Head Start double session center-based programs, 72,727 new slots would need to be created. As a result, starting in year six following publication of the final rule, we estimate costs of $584,363,052 associated with providing additional service to these children in line with the requirements of the final rule. However, this cost excludes the impact of the funding already provided by Congress in FY 2016 to expand duration. As discussed below, some of these costs will be covered by that funding.

For Head Start non-double session center-based programs, we estimate 36,355 slots would meet the 100 percent requirement by increasing only hours per day. We estimate the share of three-year-old slots is 35,746, and the share of four- and five-year-old slots is 49,821. Therefore, we estimate the cost of meeting the 100 percent requirement for these programs to be $54,419,668. For Head Start non-double session center-based programs, we estimate 199,656 slots would meet the 100 percent requirement by adding days. Therefore, we estimate the cost of meeting the 100 percent requirement for these programs to be $615,651,152. Finally, we estimate the total cost for all Head Start non-double session center-based slots to meet the 100 percent requirement, using these two approaches, is $670,070,820. However, this cost excludes the impact of the funding already provided by Congress in FY 2016 to expand duration. As discussed below, some of these costs will be covered by that funding.

In sum, the estimated total cost for Head Start double session and non-double session center-based slots to meet the 1,020 requirement is $1,254,433,872 before accounting for the $294 million in funding Congress has provided in FY 2016 to expand duration. This represents an additional $719,233,024 over the 50 percent requirement. However, because we assume that 10 percent of all programs not currently meeting the 1,020 annual hours minimum will receive a waiver to continue operating at their current level of annual hours, we reduce this estimate by 10 percent for a total cost borne by Head Start of $1,128,990,485 before accounting for the $294 million in funding Congress has provided in FY 2016 to expand duration. This represents an additional $620,549,679 over the 50 percent requirement. These costs will be realized in year six and annually thereafter, if the rule is fully implemented. As noted, Congress appropriated $294 million in FY 2016 to increase the duration of Early Head Start and Head Start programs. Thus, a substantial share of the $1,128,990,485 in costs will be absorbed by this funding, assuming this funding increase is maintained across the ten year window.

100% EXTENSION OF HEAD START CENTER-BASED DURATION: COSTS BORNE BY HEAD START

	Total DS slots	New slots needed	Cost per child	Cost
Double Session (DS)	145,454	72,727	$8,035	$584,363,052
	Slots	Average cost per child per hour (less admin)	Hours needed	Cost
Non-double session adding hours (30%) 3 year olds	35,746	$2.40	290.354	24,909,586
Non-double session adding hours (30%) 4 year olds	49,821	2.04	290.354	29,510,082
Subtotal				54,419,668
Non-double session adding days (70%)	199,656	10.62	290.354	615,651,152
Total, Excluding Duration Funding Appropriated Beginning in FY 2016				1,254,433,872
Less 10% Waiver, *Excluding* Duration Funding Appropriated Beginning in FY 2016				1,128,990,485
Total, *Including* Duration Funding Appropriated Beginning in FY 2016				865,868,545

Extension of Early Head Start Center-Based Program Duration

Similar to the approach to estimating the cost of increasing duration for Head Start, to estimate the costs associated with the requirement that Early Head Start center-based programs provide a minimum of 1,380 annual hours for all slots, we used GABI and PIR data. We excluded all programs not required to meet the 1,380 minimum. Therefore, we calculated the cost using data from Early Head Start center-based programs including American Indian and Alaska Native programs but excluded all other program options and Migrant and Seasonal Head Start. We calculated estimates for Early Head Start center-based double session and non-double session programs separately. Double session programs include a morning and afternoon session with the same teacher, therefore, we used the entire FY 2015 Early Head Start cost per child for center-based services from the GABI ($13,041). Next, we divided the current Early Head Start funded enrollment in double session programs (324, which is inflated for missing GABI data) by 2 to get a total estimated number of new Early Head Start slots that would need to be created to eliminate double sessions (162). We then multiplied the resulting number of slots by the average marginal cost per child. From these calculations, we estimate the cost of extending duration for all Early Head Start center-based double session slots to be $2,112,642. However, this cost excludes the impact of the funding already provided by Congress in FY 2016 to expand duration of Early Head Start programs. As discussed below, all of these costs will be covered by that funding.

For non-double session programs, we calculated the proportion of Early Head Start center-based non-double session slots that operate fewer than 1,380 annual hours (14,270, which is inflated for missing GABI data). First, we divided the average annual Early Head Start cost per child by the average number of hours per year provided across all Early Head Start non-double session center-based slots (1,627.61 hours) to get an average cost per hour of $8.01. Then, to account for fringe, we inflated 80% of this cost per hour by one-third (we assume no additional costs for overhead) because most programs spend approximately 80% of their budget on personnel. This results in an average cost per hour of $10.12.

Further, we assumed all Early Head Start programs would choose to increase the number of days they operate per year to meet the 1,380 annual hour requirement because most Early Head Start programs already operate for a full day. In order to estimate the costs associated with meeting the requirement for these programs, we assumed they would need the full average cost per child per hour, inflated for fringe. Then we multiplied the adjusted cost per child per hour ($10.12) by the average number of hours programs not currently meeting the 1,380 minimum would need to add (210.443 hours) by the number of slots (14,270) that we estimated would need to move to meet 1,380 annual hours to get an estimated cost of $30,390,579. However, this cost excludes the impact of the funding already provided by Congress in FY 2016 to expand duration. As discussed below, all of these costs will be covered by that funding.

In sum, the total cost for Early Head Start double session and non-double session center-based slots to meet the 1,380 requirement is $32,503,221 before accounting for the $294 million in funding Congress has provided in FY 2016 to expand duration. However, because we assume that 5 percent of all programs currently not meeting the 1,380 will receive a waiver to continue operating at their current level of annual hours, we reduce this estimate by 5 percent for a total cost borne by Head Start of $30,878,060 before accounting for the $294 million in funding Congress has provided in FY 2016 to expand duration. These costs will be realized in year three and annually thereafter. As noted, Congress appropriated $294 million in FY 2016 to increase the duration of Early Head Start and Head Start programs. Thus, the entirety of the $30,878,060 costs will be absorbed by this funding.

EXTENSION OF EARLY HEAD START CENTER-BASED DURATION: COSTS BORNE BY HEAD START

	Total DS slots	New slots needed	Cost per child (less admin)	Cost
Double Session (DS)	324	162	$13,041	$2,112,642
	Slots	Average cost per child per hour (less admin)	Hours needed	Cost
Non-double session	14,270	$10.12	210.443	$30,390,579
Total, *excluding FY 2016 duration funding*				32,503,221
Less 5% Waiver, *excluding FY 2016 duration funding*				30,878,060
Total, *including FY 2016 duration funding*				0

Start-up Costs for Extension of Center-based Programs

In addition to the cost of extending center-based programs estimated for Head Start and Early Head Start above, there are additional costs associated with facilities and other start-up activities for increasing duration. If there is adequate funding to support these requirements, there will be a period of ramp-up that most programs will need to implement the duration requirements, therefore we anticipate that a portion of any first 12-month operational award will be available for the purchase or renovation of facilities and other start-up activities before programs begin serving children at the higher duration. These costs would be subsumed in the grant awards to cover the costs estimated above. However, if the requirements are implemented in the absence of adequate additional funding, these start-up costs would represent additional costs that should be estimated here.

In order to estimate the amount of start-up costs, we rely on historical information from prior expansions in which approximately one quarter to one third of the total operating budget is needed for start-up activities. However, since non-double session slots will require significantly fewer start-up activities at a significantly lower cost, we assume that, on average, start-up activities will reflect twenty percent of the estimated cost to extend slots to meet the duration requirements. Therefore, we estimate the cost of start-up activities for meeting the Early Head Start requirement to be $6,175,612, the cost of start-up activities for meeting the 50 percent requirement in Head Start to be $101,668,161, the additional cost of start-up activities for meeting the 100 percent requirement in Head Start to be $124,109,936. Finally, we assume start-up costs will be incurred the year prior to the effective date for each duration requirement. We estimate start-up costs for all requirements will total $231,973,709.

	Cost of requirement (Incremental)	Start-up costs (20%)	Year*
EHS Requirement	$30,878,060	$6,175,612	Year 2 (2017–2018)
50% HS Requirement	508,440,805	101,668,161	Year 3 (2018–2019)
100% HS Requirement	620,549,679	124,109,936	Year 5 (2020–2021)

	Cost of requirement (Incremental)	Start-up costs (20%)	Year*
Total		231,973,709	

*Year ranges refer Head Start program years, which for these estimates, begin on August 1st of each year and end on or before July 31st.

Extension of Early Head Start Home-Based Program Duration

The final rule requires that Early Head Start home-based programs operate for a minimum of 46 weeks per year in § 1302.22(c)(1). In order to estimate the cost of this provision, we assumed the entire FY 2015 Early Head Start cost per child for home-based services from the GABI ($9,782). We then calculated the cost per week by dividing the cost per child by the average number of weeks all Early Head Start home-based programs operate (46.28), which we estimate is $211.37. We then multiplied the cost per child per week by the number of weeks programs not providing 46 weeks would need to add to meet the requirement (2.78) to calculate the cost per slot to meet the requirement ($587.60). Finally, we multiplied this cost by the funded enrollment of programs currently not meeting the requirement (15,484). We estimate the total cost of this provision to be $9,098,342. However, we also assume that 10 percent of these programs will receive a waiver to continue providing their current level of service; therefore, we estimate the total cost borne by Head Start of this provision to be $8,188,508. These costs will be realized in year two and annually thereafter.

EXTENSION OF EARLY HEAD START HOME-BASED DURATION: COSTS BORNE BY HEAD START

	Cost of meeting 46 weeks per slot	Funded enrollment not meeting requirement	Total cost	Cost reduced by 10% waiver
46 weeks for EHS home-based	$587.60	15,484	$9,098,342	$8,188,508

Head Start Home-Based Standard Option

We received comments expressing concern about our proposal in the NPRM to remove home-based services as a standard program option for Head Start. These comments are described in detail in the comment and response portion of this rule. In response to these comments, we have retained home-based services as a standard option for preschoolers in the final rule and no longer estimate costs associated with the removal of the home-based option for Head Start.

Waiver Authority for Ratios in Early Head Start Two-year-old Groups

This rule allows, for the first time, programs to request a waiver of ratios for groups with two-year-old children. We believe that programs in states that allow higher ratios for two-year-olds groups or mixed age groups may request waivers to allow them to serve more children and support continuity as children approach pre-school. We anticipate awarding waivers to programs who propose to serve two-year-old children at a ratio of 1:5 rather than 1:4, provided they have sufficient space to meet square footage requirements and can demonstrate it meets the needs of the community, the learning needs of children, and can ensure the change in ratio poses no health and safety risk. We estimate the savings associated with receipt of this waiver here.

First, we estimated the savings associated with all two-year old groups operating with a 1:5 ratio. We used the total number of two-year-olds currently being served (61,752 from PIR data) to find the number of teachers that would no longer be needed by dividing the number of two-year-olds by the current ratio of 1:4 (which yields 15,438 teachers); and then by the 1:5 ratio that would now be allowed (which yields 12,350 teachers); and taking the difference (3,088). We then multiply this number of teachers that would no longer be needed (3,088) by the average Early Head Start teacher salary of $26,491, doubled to account for fringe and overhead ($52,982) to get a total potential savings of $163,608,416. However, while we assume that 20 percent of programs will apply to waive the ratio requirements for two-year olds given our experience with the Early Head Start—Child Care Partnership grantees, we assume that only approximately 15 percent of programs currently serving two-year-olds have adequate space to accommodate the larger group size associated with a 1:5 ratio. As such, we estimate only 15 percent of programs will receive the waiver. Therefore, we estimate that the actual total savings for this provision would be $24,541,262. These costs will be realized in year one and annually thereafter. While we recognize it is possible that programs will opt to purchase, lease, or renovate new space to become eligible for this waiver, we believe the costs of such purchase, lease, or renovation would offset the savings estimated here and we lack data to support a reasonable assumption about the proportion of programs who would do so, therefore we have not estimated these costs and cost savings here.

WAIVER FOR TWO-YEAR-OLD RATIO: COST SAVINGS BORNE BY HEAD START

Total number of 2 year olds	Current number of teachers (1:4)	New number of teachers (1:5)	Number of teachers no longer needed	Average EHS teacher salary	Salary inflated for fringe and overhead	Total savings
61,752	15,438	12,350	3,088	$26,491	$52,982	$163,608,416
Total (Reduced by 85% for programs without adequate space)						24,541,262

Waiver Application Process for Locally-Designed Program Options

As discussed above, this rule includes a provision in § 1302.24 that would require any program wishing to operate a locally-designed program option to submit a waiver application explaining why the local design better meets community needs. As discussed in further detail in the discussion of the rule for § 1302.24, this waiver option will strengthen program accountability while maintaining local flexibility. The rule also includes a provision, as described above, to allow programs to request a waiver of teacher to child ratios for groups serving two-year-old children. The application process itself has a cost to grantees which is the focus of this cost estimate.

In order to estimate the cost associated with preparing and submitting waiver applications as allowed in other sections, we used GABI data to determine the total number of grantees that do not meet the new service duration minimums. Among the 1,412 Head Start grantees (which is 1,271 inflated by 11% for missing GABI data), 966 (which is 870 inflated by 11 percent for missing GABI data) do not meet the requirement to provide 1,020 annual hours to 50 percent of slots and 1,036 (which is 933 inflated by 11 percent for missing GABI data) do not meet the requirement to provide 1,020 annual hours to 100 percent of slots. Among all Early Head Start grantees, 822 programs provide center-based or family childcare services (which is 727 inflated by 13 percent for missing GABI data) and 739 programs provide home-based services (which is 656 inflated by 13 percent for missing GABI data), 275 (which is 243 inflated by 13 percent for missing GABI data) do not meet the 1,380 hours for center-based and family child care programs, and 263 (which is inflated by 13 percent for missing GABI data) do not meet the minimums for home-based programs. Finally, PIR data indicates there are 995 all Early Head Start and Migrant or Seasonal Head Start programs that currently serve two-year-olds.

We anticipate more waiver requests will be submitted than will be granted and estimate that half of the waiver requests received will be approved, which is reflected in the above calculations on increasing program duration and group ratios. Given the flexibility built into the duration requirements in the final rule, we assume that only 10 percent of Head Start grantees not meeting the 50 percent requirement will apply for a waiver (97), 20 percent of Head Start not meeting the 100 percent requirement will apply for a waiver (207), 10 percent of Early Head Start center-based grantees not meeting the new minimums will apply for a waiver (28), and 20 percent of Early Head Start home-based grantees not meeting the new minimums will apply for a waiver (53). Finally, we assume that 20 percent of programs serving two-year-olds will apply for a waiver (199), even though only 15 percent of programs will receive it. Based on these assumptions we expect a total of 199 waiver applications in year one, 252 waiver applications in year 2, 280 waiver applications in year three, 377 waiver applications in years four and five, and 487 waiver applications in year 6. Finally, we assume upon full implementation of the rule, programs would choose to reapply once every five years, resulting in an estimated 97 waiver applications annually in year 7 and ongoing.

In order to calculate the costs associated with these applications, we assume that each waiver application will require 8 hours of a program director's time at $35.36 per hour. Therefore, we calculate the cost associated with the applications by multiplying the number of applications by 8 hours of a center director's hourly wage ($285.30). Using this method, we calculate the total cost associated with these waiver provisions for each year in the table below. Then we applied the proportion of Head Start center director's salary paid for with Head Start funds (75.3 percent) to the cost by year to find the costs borne by Head Start and the costs borne by other parties in the table below.

WAIVER APPLICATIONS: TOTAL COST TO SOCIETY

	Number of programs	Hours	Cost per hour	Cost
50% HS Center-based duration	97	8	$35.36	$27,551
100% HS Center-based duration	207	8	35.36	59,093
EHS Center-based duration	28	8	35.36	7,988
EHS Home-based duration	53	8	35.36	15,121
Two-year-old ratio	199	8	35.36	56,775

The table below describes the cost to society disaggregated by costs borne by Head Start and costs borne by other parties for years three through ten. We assumed that programs would only apply for waivers once the compliance date of the provision they are requesting a waiver for has passed. Therefore, we assumed that the cost of applying for a waiver from the 50 percent Head Start center-based duration requirement would be borne in years three through five; the cost of applying for a waiver from the 100 percent Head Start center-based duration requirement would be borne in year 6; the cost of applying for a waiver from the Early Head Start center-based would be borne beginning in year 3; the cost of applying for a waiver from the Early Head Start home-based duration requirement would be borne beginning in year 2; and the cost of applying for a waiver from the Early Head Start ratio requirement would be borne beginning in year 1. Finally, we assume upon full implementation of the rule, programs would choose to reapply once every five years, resulting in the costs for years seven through ten.

WAIVER APPLICATIONS: COSTS BORNE BY HEAD START AND BY OTHER PARTIES

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Years 7–10
Cost to Society	$56,775	$71,896	$79,884	$107,435	$107,435	$138,977	$27,795
Cost to Head Start (75.3%)	42,751	54,137	60,153	80,899	80,899	104,650	20,930
Cost borne by other parties	14,023	17,758	19,731	26,537	26,537	34,327	6,865

Home Visits for Frequently Absent Children

The rule includes a new provision in § 1302.16 that requires programs to provide additional services to families of children who are frequently absent (for non-illness or IFSP/IEP related reasons), which may include a home visit. This requirement will improve consistent attendance, which is important because research demonstrates that attendance is predictive of school success. For example, one study conducted in the Chicago Public Schools shows that preschool attendance is important for several reasons: (1) It sets up patterns for long-term school attendance; (2) children who regularly attend preschool perform better on kindergarten entry assessments tests; and 3) regular attendance enhances social-emotional development.[154] Another study in Tulsa found that preschoolers who attended regularly showed more growth in literacy skills than their peers who were frequently absent.[155] In Baltimore, researchers found that 25 percent of children who were chronically absent in pre-kindergarten and kindergarten were retained in later grades, compared to nine percent of their peers who regularly attended in these early years.[156]

We considered both monetary costs as well as opportunity costs in estimating the total cost of this new provision in § 1302.16. In order to estimate the associated monetary costs, we used data from the Family and Child Experience Survey (FACES) and babyFACES, which are federally funded nationally representative surveys of Head Start and Early Head Start programs, respectively. These studies provided estimates of the proportion of children in both Head Start and Early Head Start who are absent for more than 20 days in a given school year. For Head Start, FACES data suggests 5.6 percent of children are absent for more than 20 days. We used this proportion as a proxy for the proportion of children who are frequently absent, and would trigger the requirement in the rule for an additional home visit. For Early Head Start, we assumed approximately half of this proportion would be children for whom absences were explained, given the frequency of illness among very young children and thus would not trigger this requirement. Therefore, we used half (17 percent) of the proportion from babyFACES data (34 percent) as a proxy for children in Early Head Start who are chronically absent and would thus trigger additional services, which could include an extra home visit. Then, we estimated the number of extra home visits this requirement will trigger by multiplying cumulative enrollment for center-based programs in Head Start and Early Head Start, respectively, by these proxy proportions. We estimated the monetary cost of this provision by multiplying the number of extra home visits by the average wage of a teacher and an assistant teacher for two hours, because we expect some home visits will be conducted by teachers or home visitors and others may be conducted by the family service worker (usually paid on par with assistant teachers). Finally, we assumed that only half of families would receive an additional home visit rather than other direct contact as allowed under the requirement. Using this method, we estimate the total monetary cost of this requirement to be $927,603 starting in year one. However, we also expect the activities that programs engage in to address frequent and chronic absenteeism, including home visits, will reduce the number of children who are frequently and chronically absent over time. Therefore, we have estimated a 10% reduction in the number of frequently and chronically absent children every year for the first five years this policy is in place. This results in a cost of $834,842 in year two, $742,082 in year three $649,322 in year four, $556,562 in year five and $463,801 in year six and on an ongoing basis thereafter.

To calculate the opportunity cost, we use foregone wages as an estimate for the value of parents' time spent meeting this requirement of one additional home visit. This represents the value of their time when they participate in an additional home visit rather than working. However, we acknowledge this is likely an overestimate of opportunity cost, given the potential for opportunity cost savings associated with parents' time if their children resume regular program attendance. We used the number from our estimate of children experiencing chronic absenteeism (62,858) and assumed one parent per child. Because Head Start families are primarily families from low-income backgrounds, we used the federal minimum wage and assumed two hours of time for each parent to meet this additional requirement for half of parents of chronically absent children (because parents of the other half of these children would receive other direct contact), which would result in a monetized opportunity cost of $455,721. These opportunity costs will be realized in year one. However, as discussed above, we expect these activities will reduce the number of parents of frequently and chronically absent children over time. Therefore, we estimate an opportunity cost of $410,149 in year two, $364,577 in year three $319,005 in year four, $273,433 in year five and $227,861 in year six and on an ongoing basis thereafter.

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[154] Allensworth, E.M., Ehrlich, S.B., Gwynne, J.A., & Pareja, A.S. (2013). Preschool Attendance in Chicago Public Schools: Relationships with Learning Outcomes and Reasons for Absences.

[155] Community Action Project Tulsa County. (2012). *Attendance Works Peer Learning Network Webinar.*

[156] Connolly, F., & Olson, L.S. (2012). Early Elementary Performance and Attendance in Baltimore City Schools' Pre-Kindergarten and Kindergarten. *Baltimore Education Research Consortium.*

HOME VISITS FOR FREQUENTLY ABSENT CHILDREN: COSTS BORNE BY HEAD START

Program type	National survey proxy %	FE	Estimated number of additional HVs	Avg. wage/ 2 hours	Estimated cost of all potential additional HVs	Estimated cost of additional HVs provided
HS	5.6	874,604	48,978	$30.70	$1,503,625	$751,812
EHS	17	81,649	13,880	25.33	351,580	175,790
Total						927,603
	Year 1 2016/2017	Year 2 2017/2018	Year 3 2018/2019	Year 4 2019/2020	Year 5 2020/2021	Year 6 2021/2022
Reduction Over Time	$927,603	$934,842	$742,082	$649,322	$556,562	$463,801

HOME VISITS FOR FREQUENTLY ABSENT CHILDREN: OPPORTUNITY COSTS

Total number of parents			Hourly wage forgone	Number of hours	Estimated cost for all parents	Estimated cost for parents receiving HV
62,858			$7.25	2	$911,441	$455,721
Total						455,721
	Year 1 2016/2017	Year 2 2017/2018	Year 3 2018/2019	Year 4 2019/2020	Year 5 2020/2021	Year 6 2021/2022
Reduction Over Time	$455,721	$410,149	$364,577	$319,005	$273,433	$227,861

Parent Contact for Unexpectedly Absent Children

The rule includes a new provision in § 1302.16 that requires programs to attempt to contact parents if they have not notified the program that their children will be absent. This requirement will ensure child safety and facilitate more consistent attendance for all children. The NPRM included a similar requirement, though the requirement in the final rule has been revised in response to comments. However, the Regulatory Impact Analysis in the NPRM did not account for costs associated with this requirement. In response to comments, we estimated the costs associated with contacting parents when they have not notified the program that their children will be absent in this section. In order to estimate the cost of this requirement, we assumed that 10 percent of children would be absent on any given day, which is 91,216 children when applied to the funded enrollment number for Head Start and Early Head Start programs. Then we found the proportion of Head Start children who would be absent each day (83.8% or 76,439), and the proportion of Early Head Start children who would be absent each day (16.2% or 14,777). We further assumed one-quarter of these children, 19,110 in Head Start and 3,694 in Early Head Start, would be unexpectedly absent or that their parent would not contact the program within an hour to report the absence that day. To estimate the cost of making phone calls, we assume 5 minutes of administrative staff or family service worker time per phone call resulting in 1,592 hours of staff time per day across all Head Start programs and 308 hours of staff time per day across all Early Head Start programs. As a proxy for the hourly wage of this staff person, we averaged the hourly wage of Head Start and Early Head Start assistant teachers ($11.72). Then we estimate the cost associated with this provision per day to be this hourly wage multiplied by the number of hours of staff time, which is $18,650 for Head Start programs and $3,608 for Early Head Start programs. Finally, in order to estimate the cost of this provision annually, we multiplied the cost per day by the average number of days currently provided by Head Start (146.8) for a cost of $2,737,861 per year in Head Start, and by the average number of days currently provided by Early Head Start (222.364) for a cost of $802,338 per year in Early Head Start. Finally, we summed these costs for a total cost per year across all programs of $3,540,199.

PARENT CONTACT FOR UNEXPECTEDLY ABSENT CHILDREN

	Number of absent children	Number of unexpectedly absent children	Hours of staff time (5 mins per call)	Cost per day	Cost per year
Head Start	76,439	19,110	1,592	$18,650	$2,737,861
Early Head Start	14,777	3,694	308	3,608	802,338
Total					3,540,199

Staff Quality Provisions

This rule also includes several provisions to improve the quality of staff in Head Start and Early Head Start programs. Specifically, we analyzed costs associated with the following requirements: Minimum of associate's degree for all Head Start teachers in § 1302.91(e)(2)(ii); minimum of CDA or equivalent credential for all home visitors in § 1302.91(e)(6)(i); credentials for newly hired family services workers in § 1302.91(e)(7); credentials for newly hired management staff in § 1302.91(d)(1)(i); and mentor coaching in § 1302.92(d).

Associate's Degree (AA) for Head Start Teachers

The Act detailed new degree requirements for all Head Start teachers. Specifically, 648A(a)(3)(B) of the Act codified a minimum requirement that all Head Start teachers have at least an associate's degree. While progress towards meeting this requirement has been substantial, according to PIR data, a small percentage of Head Start teachers in 2015 (4.2%) did not have such a degree. In this rule, we added this requirement into the staff qualifications section of the performance standards in § 1302.91(e)(2)(ii). Given that some teachers do not have the minimum degree, we estimated the cost associated with this requirement by finding the respective differences in average salaries for teachers with no credential and teachers with a Child Development Associate (CDA), compared to teachers with associate's degrees. We then multiplied the number of teachers who currently have no credential or the number of teachers who currently have only a CDA by the additional salary for each group. Finally, we increased the estimated salary for these teachers by one-third to account for fringe benefits (we assumed no additional overhead costs). Using this method, we estimate the total cost for Head Start programs to meet this requirement to be $10,472,585. These costs will be realized in year one and annually thereafter.

ASSOCIATE'S DEGREE FOR HEAD START TEACHERS: COSTS BORNE BY HEAD START

Current credential	Salary differential (between current and AA)	Inflated for fringe	Number of teachers	Cost of additional salary after obtaining AA
CDA	$4,535	$6,032	1,314	$7,925,457
None	3,426	4,557	559	2,547,128
Total				10,472,585

Home-Visiting Child Development Associate for Home Visitors

In this rule, we also propose to require that all home visitors have, at a minimum, a home-based CDA credential or equivalent in § 1302.91(e)(6)(i). This change will ensure that all home visitors are equipped with the critical content knowledge offered through a home-based CDA that will support their competency to implement a research-based curriculum and ensure children served in this model receive high-quality learning experiences. Because our current PIR data does not differentiate between credential types for home visitor salaries, we used a proxy of the differential percentage of salary for teachers with associate's degrees compared to teachers with CDAs. We then applied this differential percentage to the average home visitor's salary to estimate the increase in salary for home visitors who would obtain a CDA which is $6,029 when inflated by one-third to account for fringe benefits (we assumed no additional overhead costs). Finally, we multiplied this additional salary by the number of home visitors who currently have no credential. This approach gives us an estimate of the total cost of requiring higher credentials for home visitors. Using this method, we estimate the total cost of meeting this new requirement to be $5,112,499.

HOME-VISITING CDA: COSTS BORNE BY HEAD START

Current credential	Proportion of salary differential (Teachers: CDA to AA)	Avg. HV salary	Additional salary	Salary inflated for fringe	Number of HVs w/o any credential	Cost of additional salary for credentialed HVs
None	14.91%	$30,397	$4,533	$6,029	848	$5,112,499

Credential for New Family Service Workers

The final rule includes a requirement in § 1302.91(e)(7) for new family services staff who work directly with families on the family partnership process to earn a credential in family services within 18 months of hire. In order to calculate the cost associated with this requirement, we found the number of family services staff who currently do not have a credential or higher qualification (6,196) and assumed that approximately half of all family service workers work directly with families on the family partnership process for an estimate of 3,098 staff members whose replacement would need to earn a credential if the current worker left their job. We then calculated an estimate of new staff who would need to earn a credential by applying the average turnover rate of 17 percent for teachers and home visitors as a proxy (because we do not have data on turnover of family services staff) for an annual estimate of 542 staff turning over. Then we assumed the average cost for each staff person to get the necessary credential within 18 months would be

$1,013, based on an average of costs for common family development credentials. Therefore, we estimate the cost of this provision at $549,046 annually. Given the difficulty, programs may face in the future finding staff that already have this credential, we have assumed this cost will be an ongoing annual cost. Therefore, these costs will be realized in year one and annually thereafter.

CREDENTIAL FOR NEW FAMILY SERVICE WORKERS: COSTS BORNE BY HEAD START

Number of family service workers w/o credential	Proportion of staff working directly on family partnerships	Estimated turnover rate	Total staff affected annually	Cost of credential	Total estimated cost
6,196	3,098	17%	542	$1,013	$549,046

Bachelor's Degree for New Management Staff

In response to comments described in the preamble of this rule, the final rule includes a requirement in § 1302.91(d)(1) that newly hired staff who oversee health, disabilities, and family support services must have a bachelor's degree (BA). If a grantee assigns a separate area manager for each of these three service areas, it would result in three additional managers being required to hold a BA or higher. However, it is currently common practice for programs to assign the duties associated with the oversight of two service areas to a single manager. We assume that half of programs assign oversight of disabilities services to their Education Coordinator (who is already required to have a BA), which would lead to two managers (one for health and one for family support services) needing to possess BAs, and that half of programs would assign oversight of disabilities and family services or health to a single manager. Therefore, we estimate that two managers at each program will need to possess BAs to meet this requirement.

We then estimated the number of supervisors or management staff affected by the requirement who do not currently have a BA. We used data from the PIR on the education level of family services supervisors because we do not collect data on the educational attainment of other service area managers. Data indicate that 1,255 family services supervisors do not have a B.A. or higher. This estimate was then doubled based on the calculations and assumptions above for an estimate of 2,510 supervisory staff who do not currently have a B.A. or higher. Because we do not have turnover information on management staff, we then applied the average turnover rate for teachers and home visitors (17 percent) as a proxy, to the number of service managers without a B.A., in order to estimate the total number of managers without a BA that would turn-over each year (accounting for those who acquired a BA in prior years, through year ten).

Then, in order to determine the anticipated salary increase for managers with a B.A,, we averaged the current salaries for family services, health, and disabilities managers from the PIR ($44,583) and found the difference between this salary and the average salary of education coordinators ($50,252) who are currently required to have a B.A. to estimate the average increase in salary for new managers with a B.A. ($5,669). We then inflated this additional salary by one-third to account for fringe benefits (we assumed no additional overhead) which is $7,540. We then applied this difference to the number of staff affected annually. Further, we applied the average proportion of management staff salaries' borne by Head Start (67.8%) to find the cost borne by Head Start and the cost borne by other parties in years one through ten.

BACHELOR'S DEGREE FOR NEW MANAGEMENT STAFF: COSTS BORNE BY HEAD START AND BY OTHER PARTIES

Family service supervisors without BA or higher	Inflated for other service areas (2)	Estimated annual turnover rate	Estimated increase in salary
1,255	2,510	17%	$7,540
	Cost to society	Costs borne by HS	Costs borne by other parties
Year 1	$3,219,482	$2,182,809	$1,036,673
Year 2	5,865,941	3,977,108	1,888,833
Year 3	8,135,412	5,515,809	2,619,603
Year 4	10,027,894	6,798,912	3,228,982
Year 5	11,543,388	7,826,417	3,716,971
Year 6	12,870,387	8,726,123	4,144,265
Year 7	13,820,398	9,370,230	4,450,168
Year 8	14,770,409	10,014,338	4,756,072
Year 9	15,524,386	10,525,534	4,998,852
Year 10	16,089,869	10,908,931	5,180,938

Mentor Coaching

In this rule, we require programs to have a system of professional development in place that includes an intensive coaching strategy for teachers. As described in further detail in the discussion of the rule for § 1302.92(d), this change will ensure teaching staff receive effective professional development, based on a growing body of research demonstrating the effectiveness of intensive professional development for improving teacher practices in early care and education settings[157] [158] [159] and research demonstrating that such strategies support improved teacher practice in the classroom and an increase in classroom quality.[160] [161] This provision also gives programs some flexibility to identify the education staff that would benefit most from this form of intensive professional development and direct their efforts accordingly.

There are various ways that programs can secure the services of mentor coaches in order to meet this requirement. For example, grantees could hire a full-time mentor coach(es), mentor coaches could work part time in multiple programs, or geographically defined consortiums could be created to enable grantees to access the services of mentor coaches. However, for the purposes of this estimate, we use a caseload of one coach per 15 teachers or teaching teams, and an overall salary comparable to that of an education manager ($50,252 from PIR), doubled for fringe benefits and overhead, which is estimated at $100,504 for each mentor coach. We assumed a caseload of 15 teachers based on a review of the literature that suggests caseloads vary across coaching models but that full-time coaches, on average, usually reported caseloads ranging from 13 to 22, though some coaches had much higher or much lower caseloads.[162] [163] [164] We then calculated the total number of mentor coaches needed to support all education staff by using 62,495 teachers (the number of lead Head Start and Early Head Start teachers) as a proxy for the total number of teachers and teaching teams that would receive mentor coaching. We estimated the cost of providing 4,238 coaches for 63,566 teachers or teaching teams at $425,935,952. We then assume that programs will utilize their flexibility to identify education staff or teaching teams who would most benefit from this type of professional development. We believe that while the proportion of teachers and teaching teams receiving coaching will vary by program, overall this will result in approximately one-third of teaching staff receiving intensive coaching on average. Therefore, our final estimate for the cost of the requirement is $141,978,651.

Given the lack of data regarding the quality and scope of coaching strategies programs may currently be using, we do not give any credit for programs that may already utilize mentor coaches in this estimate. Further, we acknowledge that this estimate may be an underestimate if Congress appropriates the necessary additional funds to support increased duration of Head Start and Early Head Start programs because additional teaching staff will need to be hired to support the transition of double session slots to full school day and full school year slots. We estimate that an additional 3,906 teachers would need to be hired to transition all programs from double sessions, which would be associated with an additional cost of $8,723,452 and a new total cost of $150,702,102. However, this estimate may be an overestimate if the rule is fully implemented without additional funding and the Secretary does not exercise the discretion to reduce the duration requirements because the number of teachers would not increase. Therefore, a reasonable assumption for calculating this estimate is to use the status quo as the basis of the total number of education staff who may receive mentor coaching.

These costs will be realized in year two and annually thereafter.

MENTOR COACHING: COSTS BORNE BY HEAD START

Mentor coach salary, fringe and overhead	Number of teachers and FCC providers	Number of coaches	Estimate for all teachers	Estimate for ⅓ of teachers
$100,504	63,566	4,238	$425,935,952	$141,978,651

Curriculum and Assessment Provisions

This rule includes several provisions to improve curriculum and assessments. We analyzed costs associated with the following specific requirements: Improving curriculum in § 1302.32(a)(1); monitoring the fidelity of curriculum implementation in § 1302.32(a)(2); language assessment in home language and English for all dual language learners in § 1302.33(c)(2), and opportunities for parents to participate in a parenting curriculum in § 1302.51(b). We analyzed savings associated with the removal of Head Start designed IEPs from part 1308 of the previous standards.

Improving Curriculum

In this rule, we include several provisions intended to improve the quality of curricula that programs select in § 1302.32(a)(1). Specifically, these new provisions will require programs to critically analyze the curricula they use to determine whether they are appropriately aligned with and sufficiently content-rich to support growth in the domains outlined in the *Head Start Early Learning Outcomes Framework: Ages Birth to Five.* This change will ensure all programs select and implement curricula with the key qualities that research suggests are critical to promoting child outcomes.[165] [166] [167] [168] [169] [170] [171] [172] [173] For some

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[158] Tout, K., Halle, T., Zaslow, M., & Starr, R. (2009). *Evaluation of the Early Childhood Educator Professional Development Program: Final Report:* Report prepared for the U.S. Department of Education.

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[162] Howard, E.C., Rankin, V.E., Fishman, M., Hawkinson, L.E., McGroder, S.M., Helsel, F.K., et al. (2013). *The Descriptive Study of the Head Start Early Learning Mentor Coach Initiative.* OPRE Report #2014–5a; Washington, DC: U.S. Department of Health and Human Services, Administration for Children and Families, Office of Planning, Research and Evaluation.

[163] Isner, Tout, Zaslow, Soli, Quinn, Rothenberg and Burkhauser (2011). Coaching in Early Care and Education Programs and Quality Rating and Improvement Systems (QRIS): Identifying Promising Features.*www.childtrends.org/wp.../2011-35CoachingQualityImprovement.pdf.*

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Continued

programs, these new provisions may require purchasing new curricula, or purchasing curricular add-ons or enhancements.

In order to estimate the cost associated with these provisions, we assumed that education managers would need to allocate an additional thirty hours of analysis and planning time. We estimated the average hourly rate from the average annual salary of education managers and determined the total cost per manager for thirty hours. We then multiplied the cost by the total number of all programs to find a total cost to society of $1,477,847. We then found the cost borne by Head Start ($1,056,660) by applying the proportion of education manager salaries borne by Head Start funds of 71.5 percent, and then found the cost borne by other parties ($421,187). In addition, we estimated the cost of a curricular enhancement to be $4,500 for a three year multi-site license. We know that most programs routinely upgrade their curriculum or purchase a new curriculum. For this cost estimate, we assumed an average of two-thirds of programs (1,346) would identify the need to purchase additional curricular enhancements, and multiplied that number of programs by the average cost of an enhancement to estimate its total cost ($12,114,000). We then summed the cost of managerial time and curricular enhancements ($13,591,847). Since most licensing will be for three years, we assumed grantees will conduct a curriculum assessment process every three years and divided the cost by three. This results in an estimated annual cost of improving curriculum of $4,530,616, and the annual cost borne by Head Start is $4,390,220 with an annual cost borne by other parties of $140,396. These costs will be realized in year two and annually thereafter.

IMPROVING CURRICULUM: COSTS BORNE BY HEAD START AND BY OTHER PARTIES

	Avg. ed manager salary	Cost of 30 hours	Number of programs	Estimated cost to society	Costs borne by Head Start	Costs borne by other parties
Additional Staff Time	$50,252	$724.79	2,039	$1,477,847	$1,056,660	$421,187
	Avg. cost of enhancement	Number of programs	66% of programs	Estimated cost to society		
Curricular Enhancement	$9,000	2,039	1,346	$12,114,000		
				Estimated cost to society	Costs borne by Head Start	Costs borne by other parties
Total	....	....	....	$13,591,847	$13,170,660	$421,187
Annual Total	....	....	....	4,530,616	4,390,220	140,396

Monitoring Fidelity of Curriculum Implementation

In addition to the curriculum quality requirements described in the previous section, this rule also requires in § 1302.32(a)(2) that programs provide adequate supervision and regular monitoring of curriculum use to ensure effective curriculum implementation, which is critical to reaping the benefits of using high quality curricula described above.[174] [175]

In order to estimate the cost associated with this provision, we researched the cost of curriculum fidelity kits, which help programs assess how well their teachers are implementing a particular curricula through planned activities. At present, few curricula offer such a kit. However, based on those that are available, we assessed the average cost of an implementation tool kit at $50. We then multiplied that estimate by the number of programs to find the total cost of this provision. We did not estimate additional staff time, because monitoring and staff supervision was required in the previous rule and individualization of this information is included in our mentor coaching estimate. Using this method, we estimate the cost of fidelity tools for all programs to be $101,950. However, in response to comments, we modified the requirement in the final rule to provide additional flexibility for programs to determine how well their curriculum is being implemented. Therefore, we assume approximately one-third of programs will use a fidelity tool and estimate the total cost of this requirement to be $33,983. These costs will be realized in year two and annually thereafter.

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[175] Landry, S.H., Anthony, J.L., Swank, P.R., & Monseque-Bailey, P. (2009). Effectiveness of comprehensive professional development for teachers of at-risk preschoolers. *Journal of Educational Psychology, 101*(2), 448.

MONITORING FIDELITY OF CURRICULUM IMPLEMENTATION: COSTS BORNE BY HEAD START

Avg. cost of implementation tool kit	Number of programs	Estimated cost for all programs	Estimated cost of requirement
$50	2,039	$101,950	$33,983

Assessments for Dual Language Learners

In this rule, we also codify best practice in assessing dual language learners (DLL) in § 1302.33(c)(2) by requiring programs to administer language assessments to dual language learners in both English and their home language, as needed, either directly or through interpreters. These requirements will ensure that screening and assessment data is collected in both languages to ensure a more complete understanding of these children's knowledge, skills and abilities.[176] In order to estimate the costs associated with this proposal, we first determined the number of DLLs across Head Start and Early Head Start by assuming all children who speak a language other than English in the home are DLLs. We then determined the proportion of DLL children who speak Spanish in the home and the number of children who speak other languages. For the purposes of this estimate, we assume that all DLLs who speak Spanish in the home will receive a direct assessment in Spanish, and for all DLLs who speak any language other than Spanish in the home will be assessed through an interpreter. For Spanish-speaking DLLs (265,209 children), we assumed the average cost of a Spanish-language assessment tool-kit (using the most frequently reported assessment as our proxy) is $200 and the average cost per pack of 25 assessment forms is $50. We determined the total number of tool-kits needed by finding the number of programs serving at least one Spanish-speaking child (1,651). We determined the number of packs of assessment forms needed by dividing the total number of Spanish-speaking children by 25 (10,610). We then multiplied the cost of the tool-kit by the number of programs and the cost of the assessment forms by the number of children and summed them to find the total cost of this provision for children who can be directly assessed. For DLLs speaking languages other than Spanish (56,658 children), we found the average hourly rate for an interpreter from the Bureau of Labor Statistics and assumed two hours for each assessment. Finally, we doubled this hourly wage to account for fringe and overhead ($46.08) even though we assume that programs will utilize the services of interpreters on a case-by-case basis rather than employing them as program staff. We then multiplied that cost by the number of non-Spanish-speaking DLLs to find the cost of this provision for children who need to be assessed through an interpreter. Finally, we summed these two estimates to produce a total cost estimate for the provision: $3,471,519. These costs will be realized in year two and annually thereafter.

ASSESSMENTS FOR DUAL LANGUAGE LEARNERS: COSTS BORNE BY HEAD START

Type of DLL	Avg. cost of Spanish assessment	Avg. cost of 25 forms	Number of programs	Number of form packs	Estimated cost
Spanish-speaking	$200	$50	1,651	10,610	$860,700
	Avg. hourly wage for interpreter inflated for fringe and overhead	Cost/ assessment	Number of children		Estimated cost
Other	$46.08	$92.16	56,658		$5,221,638
Total					6,082,338

Screenings for Children With IEPs and IFSPs

In § 1302.33(a)(3) of the NPRM, we explicitly stated Head Start programs were not required to perform initial developmental screenings for children who enter the program with a current IEP or IFSP. However, in response to public comments expressing concern about this provision, it has been removed from the final rule and we have reinstated the existing requirement that programs must perform initial developmental screenings for all children, including those with a current IEP or IFSP. Therefore, we do not have estimates associated with this provision.

Removal of Head Start-Specific IEPs

The reauthorization of the Head Start Act in 2007 removed previously held authority for Head Start programs to create their own IEPs for children with disabilities. As a result, no programs currently create their own IEPs for children. Prior to 2007, Head Start programs frequently created such IEPs at great cost to programs. In accordance with OMB Circular A–4, we estimate the cost/savings associated with all new provisions in this final rule, including the removal of this authority and the extensive regulatory requirements that accompany it in part 1308 of the previous rule.

In order to estimate the savings associated with the removal of these provisions, we first estimated the number of children in the 2004–2005 program year whose IEP was created by Head Start, which was the last year in which the PIR collected this data. PIR data from that year indicate 14,758 children had IEPs but were not eligible for services under IDEA. We assumed, at a minimum, that the IEPs for all of these children were created through the Head Start process. In order to estimate the cost of an IEP, we first assumed 2 hours of staff time for both the Education Manager and the Disabilities Coordinator. We also assumed 4 hours of Special Education Specialist consultant work, at $50 per hour on average. We then multiplied this staff time by the number of IEPs. We also researched the cost of a multi-disciplinary evaluation and estimated, based on a sample of state estimates, the cost per IEP to be $2,500 on average. We multiplied this cost by the number of IEPs and then added it to the estimated cost of staff time to determine our total cost savings to Head Start for this policy change at $41,180,576. The entire cost savings associated with the removal of Head Start-specific IEPs is considered a transfer, because these costs will be borne by other parties, leading to a net cost to society of zero dollars. The transfer of these costs will be realized in year one and annually thereafter.

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[176] Barrueco, S., Lopez, M., Ong, C., & Lozano, P. (2012). *Assessing Spanish-English bilingual preschoolers: A guide to best approaches and measures*. Baltimore, MD: Brookes.

REMOVAL OF HEAD START-SPECIFIC IEPS: COST SAVINGS TO HEAD START AND TRANSFER COST

	Cost/hour for staff	Cost of consultation	Number of IEPs	Cost savings borne by head start	Transfer cost	Net cost to society
Staff/Consultant Time	$90.39	$200	14,758	$4,285,576	$4,285,576	$0
	Cost of evaluation		Number of IEPs	Cost savings borne by head start	Transfer cost	Net cost to society
Multi-disciplinary Evaluation	$2,500		14,758	$36,895,000	$36,895,000	$0
Total			....	41,180,576	41,180,576	0

Parenting Curriculum

This rule includes a requirement in § 1302.51(b) that programs provide parents with opportunities to participate in a parenting curriculum. The NPRM proposed this requirement but the Regulatory Impact Analysis in the NPRM did not account for any costs associated with the requirement. We have added this cost estimate in response to comments that suggested we should acknowledge the costs associated with providing these opportunities to parents here.

In order to estimate the costs associated with this provision, we researched the cost of parenting curricula online and found an average cost of $1,087 for program-level materials and $14.25 per parent booklet. We then estimated that programs would provide opportunities such that one-third of parents would participate in a parenting curriculum, which assuming one parent per child is 318,751 parent participants. We then found the total program-level cost to be $2,216,393 and the total parent-level cost to be $4,542,202, for a total cost of $6,758,595. However, given recent data[177] that suggests that 41% of Head Start and Early Head Start parents already participate in parenting classes, we reduce this estimate by 40% for a total cost of $4,055,157.

PARENTING CURRICULUM

Average program-level cost of curriculum	Number of programs	Average cost per parent	Participating parents (one-third)	Total cost
$1,087	2,039	$14.25	318,751	$6,758,595
Reduced by 40%	....	....	....	4,055,157

Administrative/Managerial Provisions

This rule includes several provisions to improve important managerial and administrative responsibilities, and to reduce unnecessary administrative burden. We analyzed costs associated with the following specific requirements: Memoranda of understanding in § 1302.53(b)(1); background checks in § 1302.90(b); mediation and arbitration of disputes between the governing body and policy council in § 1301.6; data management requirements in § 1302.53(b)(2) and (3), participation in Quality Rating Improvement Systems and participation in State longitudinal data systems in § 1302.53. We analyzed savings associated with the following specific requirements: Removal of annual audits; removal of delegate appeal process at the federal level; clarification of the facilities application process in § 1303.40; revision of community needs assessment in § 1302.11(b)(1); and revision of managerial planning in § 1302.101(b).

Memoranda of Understanding (MOU)

This rule includes a new requirement that programs establish formal agreements with the local entity responsible for publicly funded preschool in § 1302.32. This change reflects a provision of the Act that requires MOUs and has been in effect since 2008. Nonetheless, per the OMB Circular Requirements for Regulatory Impact Analysis, we must estimate the costs associated with the provision, as though no programs have implemented the statutory change.

In order to estimate the costs associated with meeting this new requirement, we first estimated that establishing an MOU with such entities will require approximately 2 hours of management time, based on grantee experience implementing similar MOUs. To estimate the cost of that time, we multiplied the average hourly salary of all management positions by 2. We then multiplied that cost by the total number of programs. Using this method, we estimated the total cost associated with this requirement to be $90,185. We then estimated the proportion of the estimated cost borne by Head Start by applying the average proportion of these management wages borne by Head Start

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[177] Auger, A. (2015). *Child Care and Community Services: Characteristics of Service Use and Effects on Parenting and the Home Environment*, Ph.D. dissertation. University of California-Irvine School of Education.

(68.2 percent), and found $61,506 is borne by Head Start and the remaining $28,679 is borne by other parties. This may be an over-estimate of cost given that one purpose of the MOU is to better coordinate and share local resources, which may lead to savings, associated with implementation of the MOU. These costs will be realized in year one only.

MEMORANDA OF UNDERSTANDING: COSTS BORNE BY HEAD START AND BY OTHER PARTIES

Avg. wage for 2 hours of management time	Avg. cost of wage borne by Head Start	Number of programs	Estimated total cost	Costs borne by Head Start	Costs borne by other parties
$44.23	$30.23	2,039	$90,185	$61,506	$28,679

Criminal Background Checks

This rule includes two new provisions that strengthen the requirements programs currently must meet with regard to criminal background checks for staff in § 1302.90(b). These changes will provide alignment across federal programs about the importance and key characteristics of comprehensive background checks, which are critical to ensuring child safety in all early care and education settings. Specifically, the first provision requires programs perform both a state and FBI criminal background check on all new employees prior to hire, whereas the previous rule only required programs to perform one of the two checks. The second provision requires programs to renew criminal background checks for all employees once every five years. The FBI estimates the average cost of a criminal background check is $30. The cost of state background checks varies significantly, with some states charging more than $30. However, some states cover costs of the checks for early care providers and other states reduce costs for a combined FBI and state check. Therefore, we assume $50 to be the average cost of both the FBI and state background check, together, based on information from the Office of Child Care's CCDF State Plans, in producing our cost estimate. We also assume a $5 cost for checks of Child Abuse and Neglect registries. The national sex offender registry can be checked online, free of charge.

We considered both monetary costs and opportunity costs when estimating the cost of the first provision. To estimate the monetary cost of requiring both FBI and state background checks for new hires, we used the average turnover rate of teachers and home visitors from the PIR data (17 percent) and applied it to all staff to estimate the average number of new hires due to turnover per year. We then multiplied the number of new hires (36,438) by the average cost of the FBI background check ($30) to estimate the cost associated with this provision ($1,275,330).

In addition to these monetary costs, we also estimated the opportunity cost for new employees prior to hire to meet this requirement. This represents the value of time (measured as forgone earnings) of a prospective employee during the time, they spend to complete a background check. To calculate the opportunity cost, we averaged the hourly wage for a teacher and an assistant teacher of $15.35, multiplied it by 1.5 hours for the estimated time it would take, and multiplied that by the average number of new hires due to turnover per year. We estimate the total opportunity cost for this provision to be $838,985.

To estimate the cost of the second provision, we estimated the number of staff that would need a background check renewal every five years by dividing the total number of staff for all grantees by 5. Then we multiplied the cost of a full background check ($55) by number of staff needing a background check renewal per year (48,584) for a total cost of $2,672,120.

In addition, we estimated the cost associated with administrative staff time to process each additional background check. To calculate this, we used the applicable number of staff that would need additional background checks per year both through renewal and additional checks as staff turnover (85,022) and divided that number by 6 assuming each application will take approximately 10 minutes to process. This provided an estimate for the number of hours that administrative staff time to process additional background checks (12,265) annually. Finally, we multiplied the number of hours by the hourly wage of an administrative assistant, which we assumed to be the same rate as teacher assistants ($11.99), to estimate the total cost of processing at $169,898.

Using this method, we estimate the total monetary costs associated with the background check provisions to be $4,117,348 and the total opportunity cost to be $838,985. These costs will be realized in year two and annually thereafter.

CRIMINAL BACKGROUND CHECKS: COSTS BORNE BY HEAD START

Provision	Avg. cost of check	Total number of staff	Applicable staff	Estimated cost
Initial Comprehensive Background Check	$35	242,918	36,438	$1,275,330
5-year Renewal	55	242,918	48,584	2,672,120
	Hourly wage	Applicable staff	Number of hours	Estimated cost
Staff time to process checks	$11.99	85,022	14,170	$169,898
Total				4,117,348

CRIMINAL BACKGROUND CHECKS: OPPORTUNITY COSTS

Provision	Avg. hourly wage	Estimated time in hours	Total wage cost	Applicable staff	Estimated cost
FBI and State Check	$15.35	1.5	$23.03	36,438	$838,985
Total					$838,985

Mediation and Arbitration

The rule includes a requirement in § 1301.6(b) and (c) that agencies unable to resolve impasses through their own decision-making process must participate in a formal process of mediation. If agencies do not reach a resolution with a mediator, they must pursue arbitration and the arbitrator's decision is final. We assume few grantees will reach an impasse and fewer grantees will be unable to resolve the impasse with their own decision-making process. For purposes of estimating the costs of these provisions, we assume one percent of programs, or 20 programs, will pursue mediation—likely an overestimate—and ten percent of those, or 2 programs, will go on to pursue arbitration. According to data from the National Arbitration Association, the costs of mediation vary but are significantly lower than arbitration. They cite the costs of arbitration services range from $200 to $700 per hour. To estimate the cost, we average the hourly cost and assume $450 per hour. The National Arbitration Association also states that arbitration usually takes no more than two weeks. Therefore, we assume 80 hours at $450 per hour for three programs for a total cost of $72,000. For mediation, we assume half the cost of arbitration (both hourly rate ($225) and length of time (40 hours)), which is consistent with estimates we saw elsewhere. We assumed 20 programs would pursue mediation for a total cost of $261,000. The total for these two provisions is $333,000. These costs will be realized in year one and annually thereafter.

MEDIATION AND ARBITRATION: COSTS BORNE BY HEAD START

Provision	Avg. hourly cost	Number of hours	Number of programs	Estimated cost
Mediation	$225	40	20	$261,000
Arbitration	$450	80	2	72,000
Total				333,000

Removal of Annual Audits

This rule eliminates the separate audit requirement for Head Start programs in the previous standards in § 1301.12 in favor of aligning with the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards (Uniform Guidance, 2 CFR part 200). This change will eliminate unnecessary burden on small grantees and the Office of Head Start. The Omni Circular requires a Single Audit of entities if their total federal expenditures exceed $750,000. As a result of this $750,000 threshold, there are 18 grantees that will no longer be required to have an audit. Using an estimate of $17,000 per audit per the suggestion of regional grants management staff who oversee audit procedures, we estimate a savings of $306,000. These costs will be realized in year one and annually thereafter.

REMOVAL OF ANNUAL AUDITS: COST SAVINGS BORNE BY HEAD START

Cost per audit	Number of programs	Estimated savings
$17,000	18	$306,000

Parent Committees

We received comments expressing concern about the removal of the requirement that agencies establish parent committees. As a result, we restored this requirement in the final rule. Therefore, there are no monetary or opportunity cost savings associated with the removal of parent committees in the final rule.

Delegate Appeals

This rule aligns with section 641A(d) of the Act, by only requiring grantees to establish procedures for a delegate agency to appeal a defunding decision, which the Act established. As a result, we eliminate the process by which current delegates can appeal grantee decisions to HHS, as outlined in § 1303.21. This change will eliminate unnecessary burden on grantees and the Office of Head Start. To estimate the savings associated with the removal of this process, we determined the number of delegate appeals that have occurred across ACF's 12 regions over two years (25) and then divided that number by two to find the average number of appeals annually (12.5). We obtained an estimate from a grantee on the costs of their individual appeal ($66,691) and multiplied it by two to factor in both the cost to the grantee and the delegate agency of the appeal process. We then divided that total by two based on the assumption that half of the costs are spent on the HHS phase of the appeal, which we removed. We then multiplied the average cost by the average number of appeals per year (12.5) to arrive at the annual savings. We estimate savings of $833,638 because of this change. These savings will be realized in year one and annually thereafter.

DELEGATE APPEALS: COST SAVINGS BORNE BY HEAD START

Average savings from removal of HHS phase per appeal	Number of delegate appeals/year	Estimated savings
$66,691	12.5	$833,638

Clarification of Facilities Application Process

This rule reorders the application requirements for funds to purchase, construct or renovate facilities to align with typical project development in § 1303.40. In doing so, we anticipate savings associated with grantees who are likely to identify unfeasible projects more quickly prior to soliciting costly professional advice or unnecessary testing (*e.g.* environmental), referred to as soft costs. To estimate the savings associated with these revisions, we assumed a per project cost for facilities projects of $500,000, based on our experience with facilities costs.

Since the savings would come from the soft costs that grantees incur at the beginning of a project—which under our reordered application process could be avoided for projects that grantees realize more quickly are not fundable—we assume that approximately 30 percent of the average per project costs, or $150,000 are for soft costs. Our data systems do not capture the number of applications for facility projects each year, so as a proxy, we used the total number of facilities with federal interest for the past 11 years, which is the timeframe for which we have data, with that total (4,051) divided by 11 for the number of facilities with federal interest per year (368). Based on historical data, we then estimate that 8 percent of the 368 facilities with federal interest (29 facilities projects) submit un-fundable applications annually. As a result, we then multiplied the $150,000 in estimated soft costs by 29 projects to determine the savings that would result if those grantees realized the unfeasibility of their projects earlier and never spent those funds. We estimate the total savings associated with these revisions to total $4,350,000. These costs will be realized in year one and annually thereafter.

CLARIFICATION OF FACILITIES APPLICATION PROCESS: COST SAVINGS BORNE BY HEAD START

Avg. cost of facility project	Avg. "soft" costs	Facilities with federal interest/year	Unfundable facility applications/ year	Estimated savings
$500,000	$150,000	368	29	$4,350,000

Community Assessment

This rule also includes provisions that change the previous requirement for programs to conduct full community assessments from every three years to every five years in § 1302.11(b)(1). This change will streamline the community assessment process and eliminate unnecessary burden on grantees and the Office of Head Start. We estimated the current cost of the community assessment and assumed a reduction in costs of 40 percent, based on the change from three to five years. To determine the average cost of a community assessment, we incorporated grantee feedback about both the frequency with which they choose to perform the assessment internally versus hiring consultants, and the average cost, in staff time and consultant fees, respectively of those assessments. From this feedback, we assumed 75 percent of programs (1,529) perform their community assessments using Head Start staff, while the remaining 25 percent (510) hire consultants.

We estimated the costs associated with Head Start staff time for 75 percent of programs by calculating the average hourly wage of the entire management team (for the director, education manager, health services manager, family services manager and disabilities coordinator combined), and assumed 40 hours of the entire management team's time to complete the assessment ($4,965). Note, this is likely an overestimate because many programs do not have discrete managers for each service type. We then multiplied the cost of these 40 hours by the number of programs using Head Start staff to complete their assessments for a total estimated cost to complete the assessment of $7,591,485. We then divided this cost by 3 to get the previous annual cost ($2,530,495) and by 5 to get the new annual cost ($1,518,297) and found the difference to determine the total annual savings for this approach ($1,012,198).

We estimated the costs associated with consultants for 25 percent of programs by the average cost for a consultant to perform the community assessment at $6,000 and assumed an additional 10 hours of the management team's time to support the completion of the assessment ($1,241). We then multiplied these costs by the number of programs who choose to hire consultants for their community assessment for a total estimated cost to complete the assessment of $3,692,910. We then divided this cost by 3 to get the previous annual cost ($1,230,970) and by 5 to get the new annual cost ($738,582) and found the difference to determine the total annual savings for this approach ($492,388). Finally, we summed the savings from these approaches to find the estimated the savings for this policy change to be $1,504,586. We then applied the proportion of management staff salaries paid for with Head Start funds of 67.9 percent to find the total estimated savings borne by Head Start of $1,152,558 and the estimated savings borne by other parties of $352,028. These cost savings will be realized in year one and annually thereafter.

COMMUNITY ASSESSMENT: COST SAVINGS BORNE BY HEAD START AND BY OTHER PARTIES

Option	Cost	Number of programs	Total cost	Previous annual cost	New annual cost	Difference (total savings)	Cost savings borne by head start	Cost savings borne by other parties
External:								
Staff time	$1,241	510	$632,910	$210,970	$126,582	$84,388	$57,324	$27,064
Consult Time	6,000	510	3,060,000	1,020,000	612,000	408,000	408,000	....
Internal:								
Staff time	4,965	1,529	7,591,485	2,530,495	1,518,297	1,012,198	687,234	324,964
Total	....	....	....	....	....	1,504,586	1,152,558	352,028

Managerial Planning

This rule includes two new provisions that lessen the administrative planning burden on programs by reducing the number and prescriptiveness of planning processes that are required in § 1302.101(b). Specifically, the first provision reduces current planning topics from four in the previous rule (education, health, family and community partnerships, and program design and management) to two. The second provision significantly reduces the prescriptiveness of the disabilities services plan and as a result significantly reduces the costs associated with the requirement for that planning.

In order to estimate the costs associated with the first provision, we assumed the four plans required in the existing rule took approximately two weeks of the education manager's time to develop. Our proposed provision would reduce the number of required plans by half. As a result, we assume one week of the education manager's salary as cost savings for each program. Then we multiplied this salary by the number of programs to estimate the savings associated with this provision. Further, we applied the proportion of the education manager's salary paid for with Head Start funds (71.5 percent) to determine the cost savings to Head Start and the cost savings borne by other parties. For the second provision, we assumed the disabilities service plan as outlined in the previous rule took an average of one week of the disabilities coordinator's time. We also assume that the changes to this provision will result in an 80 percent decrease in burden, and as such, estimate the cost savings per program to be 80 percent of the disabilities coordinator's average weekly wage. We then find estimated cost savings associated with this provision both to Head Start and to other parties by multiplying this amount by the total number of programs and applying the proportion of disabilities coordinator's salaries paid for with Head Start funds (64.9 percent). Finally, we sum these two cost savings to find the total estimated cost savings for this policy change to be $3,341,921, the total cost savings borne by Head Start to be $2,298,905, and the total cost savings borne by other parties to be $1,043,016. These costs will be realized in year one and annually thereafter.

MANAGERIAL PLANNING: COST SAVINGS BORNE BY HEAD START AND BY OTHER PARTIES

Cost	Cost of staff time/ week	Savings per program	Number of programs	Estimated cost savings	Cost savings borne by head start	Cost savings borne by other parties
Reduction of Plans	$966		2,039	$1,969,674	$1,408,317	$561,357
Revision of Disabilities Plan	841	$673	2,039	1,372,247	890,588	481,659
Total				3,341,921	2,298,905	1,043,016

Data Management

This rule includes several new requirements related to data management, privacy, and data governance in § 1302.53(b)(2) and (3), § 1302.101(b)(4), and part 1303, subpart C. Specifically, these provisions require that programs establish procedures related to the availability, usability, integrity, and security of data and communicate, cooperate, and share information among agencies and their community partners. For the purposes of estimating the costs of these provisions, we focus on three major elements: Designing and implementing a program-wide coordinated approach to data management and sharing data with other programs and systems through parental consent and memoranda of understanding.

First, we estimated the cost to programs of designing and implementing a program-wide coordinated approach to data management. We assumed one full day (eight hours) of planning time, using a cumulative hourly wage of $123.81 for management staff for all 2,039 programs. This resulted in a cost of $2,019,589. We then applied the proportion of management salaries paid for with Head Start funds (67.9 percent) to estimate the total cost borne by Head Start and the costs borne by other parties for this provision. We estimate the total cost to Head Start to be $1,371,301 and the cost to other parties to be $648,288.

Second, we estimated the cost of sharing data in order to coordinate with other programs and systems. We assumed these costs entail costs associated with Head Start staff time requesting parental consent to share data and establishing Memoranda of Understanding (MOU). We assume that the parental consent process would be performed by family services workers; however, since we do not have PIR data on a family service worker's hourly wage, we averaged the hourly wage of Head Start teachers and assistant teachers as a proxy for the family service worker wage ($15.35). To calculate the cost of the parental consent process, we further assumed that each consent process would take 20 minutes of the family service workers' time and divided that hourly wage by three to arrive at the cost of each parental consent ($5.12). Then, we multiplied the cost per consent by the number of parents from the PIR (988,923), for an estimated cost of $5,063,286.

We also estimated the cost of the MOU process for all programs. To do so, we averaged the hourly wages of management staff and assumed an average of three MOUs per program. We chose three MOUs based on the assumption that most programs would have an MOU with an educational agency, a local social services agency, and some other community partner. We assumed two hours of a management staff time per MOU. We used an average hourly wage for managers of $24.76 and multiplied it by two hours per each of three MOUs for an estimated cost of $148.56 per program. Then we multiplied this cost by the total number of programs (2,039) for an estimated cost of $302,914 for the MOU process. We then applied the proportion of management salaries paid for with Head Start funds (67.9 percent) to estimate the total cost borne by Head Start and the total cost borne by other parties for the MOU process. The cost borne by Head Start is $205,680, and the cost borne by other parties is $97,234.

In sum, the total estimated cost of this provision is $7,385,789, the total estimated cost borne by Head Start is $6,643,811, and the total estimated cost borne by other parties is $741,978. These costs will be realized in year two and annually thereafter.

In addition to monetary costs, we also estimated the opportunity cost associated with parents' time spent completing the parental consent process. To calculate this opportunity cost, we use foregone wages as an estimate for the value of parents' time. This represents the value of their time when they participate in an additional home visit rather than working. Because Head Start families are primarily families from low-income backgrounds, we used the federal minimum wage and assumed twenty minutes of time for one parent from each family served (988,923 according to 2015 PIR data) to meet this requirement. Therefore, we estimate the opportunity cost associated with this provision to be $2,393,194. This cost will be realized in year two and annually thereafter.

DATA MANAGEMENT: COSTS BORNE BY HEAD START AND BY OTHER PARTIES

	Cost of staff time	Number of program/ families	Total estimated cost	Costs borne by head start	Costs borne by other parties
Coordinated Approach	$990.48	2,039	$2,019,589	$1,374,845	$644,744
Consent Process	5.12	988,923	5,063,286	5,063,286	....
MOU Process	$148.56	2,039	302,914	205,680	97,234
Total	....	....	7,385,789	6,643,811	741,978

DATA MANAGEMENT: OPPORTUNITY COST

	Value of parent time/ hour	Number of parents	Time spent per parent	Opportunity cost
Consent Process	$7.25	988,923	20 minutes	$914,216
Total	....	....	....	2,393,194

Participation in Quality Rating Improvement Systems

This rule includes a new requirement that programs participate in their State's Quality Rating and Improvement System if it meets several indicators described in § 1302.53, including that the State accepts Head Start monitoring data as evidence that programs meet requirements to be assigned a rating in the State's tiered system. As a result, we estimate costs associated with both management staff time spent determining whether their state QRIS meets the indicators which would trigger participation and management staff time spent preparing monitoring reports and filling out paperwork to file with the State. We also estimate a cost to States associated with reviewing Head Start program documentation and assigning a rating to each program. While we acknowledge that there may be additional costs to Head Start and other parties associated with Head Start programs who seek to move up within a state's tiered system, for example by opting to participate in observational ratings such as the Early Childhood Environmental Rating Scale (ECERS), programs are not required to do so by this provision and we do not have data to support a reasonable assumption of how many programs would choose to do so. Therefore we have not estimated these costs here. Further, we assume that programs that choose to participate in such activities to move up within a state's system would do so in order to reap benefits such as increased subsidy reimbursement rates or access to professional development opportunities, which would, from the program's perspective, offset the costs involved. (From the perspective of society as a whole, changes in reimbursement amounts are transfers, increased resources devoted to professional development are costs, and any improved outcomes for Head Start students that result from the professional development are benefits.)

In order to calculate the costs associated with each program determining whether the QRIS in their State meets the indicators, we assumed eight hours of assessment time for the entire management team, using a cumulative hourly wage of $124.13 for management staff for all 2,039 programs. This resulted in a cost of $2,024,809. We then applied the proportion of management salaries paid for with Head Start funds (67.9 percent) to estimate the total cost borne by Head Start and the costs borne by other parties for this provision. We estimate the total cost to Head Start to be $1,367,272 and the cost to other parties to be $657,537.

Then to estimate the cost of program participation in QRIS in states that meet the indicators described in § 1302.53, we first assumed that the Program Director and the Education Manager (whose hourly wage is a total of $59.82, $40.28 of which is borne by Head Start and $19.55 of which is borne by other parties) in programs participating in QRIS would spend 16 hours (or two full days) preparing monitoring reports and filling out paperwork to file with the State. This calculation results in an estimated cost borne by Head Start of $644.42 per program and an estimated cost borne by other parties of $312.73 per program. Then, to estimate the cost per year, we had to make assumptions about what percent of programs would be in States that meet the described in § 1302.53. Although we do not think most States currently meet these indicators, we assume that States who want Head Start programs to participate in QRIS will make adjustments to their systems over time to meet the indicators such that the Head Start performance standards require participation. Therefore, we assumed that 25% of programs would participate in the first year this requirement is in place (2017/2018), 50% would participate five years after the requirement is in place (2022/2023) and that by 2025/2026 75% of programs would participate. To estimate the cost in each year, we multiplied the number of programs participating (510 in 2017/2018, 1,020 in 2022/2023, and 1,529 in 2025/2026). This results in costs borne by Head Start of $328,656 in 2017/2018, $657,311 in 2022/2023, and $985,323 in 2025/2026; and costs borne by other parties of $159,493 in 2017/2018, $318,985 in 2022/2023, and $478,165 in 2025/2026.

Then, we further assume additional costs borne by other parties, in costs to the State associated with reviewing Head Start program documentation and assigning a rating to each program. In order to estimate these costs, we assumed 8 hours of administrative staff time using the average hourly wage for administrative assistants from the Bureau of Labor Statistics 2015 data ($17.55) for a cost of $140.40 per program participating in QRIS. We then applied this cost per program to the number of programs participating in each year as described above to find the cost borne by States to be $71,569 in 2017/2018, $143,138 in 2022/2023, and $214,707 in 2025/2026.

In sum, the total costs associated with meeting this requirement which are borne by Head Start programs are $1,695,928 in 2017/2018, $2,024,583 in 2022/2023, and $2,352,595 in 2025/2026. Finally, the total costs associated with meeting this requirement which are borne by other parties are $888,598 in 2017/2018, $1,119,660 in 2022/2023, and $1,350,409 in 2025/2026.

PARTICIPATION IN QRIS: COSTS BORNE BY HEAD START AND BY OTHER PARTIES

	Cost of staff time per program	Number of programs	Total estimated cost	Costs borne by head start (67.9%)	Costs borne by other parties
Determining Participation	$993.04	2,039	$2,024,809	$1,367,272	$657,537

PARTICIPATION IN QRIS: COSTS BORNE BY HEAD START AND BY OTHER PARTIES

	Cost of staff time per program	Number of programs	Estimated cost for 25% of programs		Estimated cost for 50% of programs		Estimated cost for 75% of programs	
			To Head Start	To other parties	To Head Start	To other parties	To Head Start	To other parties
HS Management Staff for Participating Programs	$957.15	2,039	$328,656	$159,493	$657,311	$318,985	$985,323	$478,165
State Administrative Staff	$140.40	2,039	n/a	$71,569	n/a	$143,138	n/a	$214,707

PARTICIPATION IN QRIS: COSTS BORNE BY HEAD START AND BY OTHER PARTIES

	Year 2 2017–2018	Year 3 2018–2019	Year 4 2019–2020	Year 5 2020–2021	Year 6 2021–2022	Year 7 2022–2023	Year 8 2023–2024	Year 9 2024–2025	Year 10 2025–2026
Total Costs to Head Start	$1,695,928	$1,695,928	$1,695,928	$1,695,928	$1,695,928	$2,024,583	$2,024,583	$2,024,583	$2,352,595
Total Costs to Other Parties	888,598	888,598	888,598	888,598	888,598	1,119,660	1,119,660	1,119,660	1,350,409

Participation in State Longitudinal Data Systems

This rule includes a new requirement in § 1302.53 that programs should participate in State longitudinal data systems if they can participate and benefit in a similar fashion to other early childhood programs. As a result of the conditions for participation to be required, we estimate costs associated with both management staff time spent determining whether they should participate in State longitudinal data systems and qualified staff (such as a data analyst or the Education Manager) time spent preparing program data to be shared with the State. We also estimate a cost to States associated with integrating Head Start data into the state system. While we acknowledge that the cost of maintaining State longitudinal data systems can be costly to States, there is no evidence to suggest that States have passed these costs on to programs that contribute their data to the system. In this estimate, we have not estimated costs to Head Start programs associated with any fee for participation. If States began to pass these maintenance costs on to participating programs the costs presented below would represent an underestimate of the actual costs to Head Start programs and an equal-magnitude overestimate of the costs to other parties.

In order to calculate the costs associated with each program determining whether the to participate in State longitudinal data systems, we assumed four hours of assessment time for the entire management team, using a cumulative hourly wage of $124.13 for management staff for all 2,039 programs. This resulted in a cost of $1,012,404. We then applied the proportion of management salaries paid for with Head Start funds (67.9 percent) to estimate the total cost borne by Head Start and the costs borne by other parties for this provision. We estimate the total cost to Head Start to be $683,636 and the cost to other parties to be $328,768.

Then to estimate the cost of program participation in State longitudinal data systems, we first assumed that staff with qualifications and a salaries equivalent to the Education Manager, who may or may not be the Education Manager (whose hourly wage is a total of $24.16, $17.27 of which is borne by Head Start and $6.89 of which is borne by other parties) in programs participating in State longitudinal data systems would spend 40 hours (or one full week) preparing program data to be shared with the State. This calculation results in an estimated cost borne by Head Start of $690.97 per program and an estimated cost borne by other parties of $275.42 per program. Then, to estimate the cost per year, we had to make assumptions about what percent of programs would participate. Given the costly nature of maintaining State longitudinal data systems for States, and the scarcity of grant funds to support these activities, we have assumed only a small proportion of programs will be in States who have longitudinal data systems that meet the conditions described in § 1302.53 the first year this requirement is in place. Further, we assume only modest growth in the proportion of programs in such States over time. Therefore, we assumed that 10% of programs would participate in the first year this requirement is in place (2017/2018), 20% would participate five years after the requirement is in place (2022/2023) and that by 2025/2026 30% of programs would participate. To estimate the cost in each year, we multiplied the number of programs participating (204 in 2017/2018, 408 in 2022/2023, and 612 in 2025/2026). This results in costs borne by Head Start of $140,957 in 2017/2018, $281,914 in

2022/2023, and $422,871 in 2025/2026; and costs borne by other parties of $56,186 in 2017/2018, $112,371 in 2022/2023, and $168,557 in 2025/2026.

Then, we further assume additional costs borne by other parties, in costs to the State associated with integrating Head Start data into the state system. In order to estimate these costs, we assumed 4 hours of administrative staff time using the average hourly wage for administrative assistants from the Bureau of Labor Statistics 2015 data ($17.55) for a cost of $70.20 per program participating in State longitudinal data systems. We then applied this cost per program to the number of programs participating in each year as described above to find the cost borne by States to be $14.314 in 2017/2018, $28,628 in 2022/2023, and $42,941 in 2025/2026.

In sum, the total costs associated with meeting this requirement which are borne by Head Start programs are $824,593 in 2017/2018, $965,550 in 2022/2023, and $1,106,507 in 2025/2026. Finally, the total costs associated with meeting this requirement which are borne by other parties are $399,268 in 2017/2018, $469,767 in 2022/2023, and $540,267 in 2025/2026.

PARTICIPATION IN STATE LONGITUDINAL DATA SYSTEMS: COSTS BORNE BY HEAD START AND BY OTHER PARTIES

	Cost of staff time per program	Number of programs	Total estimated cost	Costs borne by head start (67.9%)	Costs borne by other parties
Determining Participation	$496.52	2,039	$1,012,404	$683,636	$328,768

PARTICIPATION IN STATE LONGITUDINAL DATA SYSTEMS: COSTS BORNE BY HEAD START AND BY OTHER PARTIES

	Cost of staff time per program	Number of programs	Estimated cost for 10% of programs		Estimated cost for 20% of programs		Estimated cost for 30% of programs	
			To Head Start	To other parties	To Head Start	To other parties	To Head Start	To other parties
HS Management Staff for Participating Programs	$690.97	2,039	$140.957	$56,186	$281,914	$112,371	$422,871	$168,557
State Administrative Staff	70.20	2,039	n/a	14,314	n/a	28,628	n/a	42,941

PARTICIPATION IN STATE LONGITUDINAL DATA SYSTEMS: COSTS BORNE BY HEAD START AND BY OTHER PARTIES

	Year 2 2017–2018	Year 3 2018–2019	Year 4 2019–2020	Year 5 2020–2021	Year 6 2021–2022	Year 7 2022–2023	Year 8 2023–2024	Year 9 2024–2025	Year 10 2025–2026
Total Costs to Head Start	$824,593	$824,593	$824,593	$824,593	$824,593	$965,550	$965,550	$965,550	$1,106,507
Total Costs to Other Parties	399,268	399,268	399,268	399,268	399,268	469,767	469,767	469,767	540,267

Implementation of Changes in the Program Performance Standards

This rule includes numerous changes to Head Start's Program Performance Standards. As a result, we have included provisions in § 1302.103 that require programs to develop a program-wide approach to prepare for and implement these changes, in order to ensure their effectiveness. In order to estimate the cost associated with these provisions, we estimated the costs associated with Head Start staff time by calculating the average hourly wage of the entire management team (for the director, education manager, health services manager, family services manager, and disabilities coordinator combined), and assumed 40 hours of the entire management team's time to develop the approach ($4,965). Note, this is likely an overestimate because many programs do not have discrete managers for each service type. Using this method we estimate the total cost of this provision at $10,123,635. We then applied the average proportion of management salaries paid for with Head Start funds (67.9 percent) to estimate the total cost borne by Head Start ($6,873,948) and the total cost borne by other parties ($3,249,687) for planning.

Further, we expect there will be costs associated with printing and distribution of hardcopies of the standards to every grantee. We estimate the cost of printing and distribution will be $75,000, based on the cost associated with printing and distributing the new *Head Start Early Learning Outcomes Framework: Birth to Five,* which was similar in length and was distributed to the same entities at a cost of $75,000. Including this cost, the total estimated cost of implementation planning is $10,198,635, the cost borne by Head Start is $6,948,948 and the cost borne by other parties is $3,249,687. We then divided the cost borne by Head Start and the cost borne by other parties in half, because we believe implementation planning will be spread across two years. Therefore, these costs will be realized in years one and two only.

IMPLEMENTATION PLANNING: COSTS BORNE BY HEAD START AND BY OTHER PARTIES

	Hourly rate of management team	Cost 40 of hours	Number of programs	Estimated cost	Estimated cost per year	Annual costs borne by Head Start	Annual costs borne by other parties
Management Time	$124.13	$4,965	2,039	$10,123,635	$5,061,818	$3,436,974	$1,624,843
Printing and Distribution				75,000	32,500	32,500	0
Total				10,198,635	5,099,318	3,474,474	1,624,843

3. Benefits Analysis

Overall, the policies included in this final rule are designed to strengthen Head Start quality, improve child outcomes, and increase the return on taxpayer dollars. As discussed in more detail in the preamble for this final rule, these policies will improve teaching practices, through implementation of content-rich curriculum, effective use of assessment data, and strong professional development. These improvements are central to our effort to ensure every child in Head Start receives high quality early learning experiences that will build the skills they need to succeed in school and beyond. In order to maximize the effectiveness of Head Start and yield a high rate of return on investment, we believe it is essential to pair these improvements to the early learning experiences provided by Head Start with increases in program duration.

In this section, as part of our full regulatory analysis, we describe our expectation that this rule will result in a greater return on the federal investment in Head Start and outline our rationale. To do so, we first consider long-standing economic analysis of the return on investment through benefits to society of high quality early education and summarize the research linking the most costly provisions—extending program duration—to the expectation for increased return on investment. Then, we describe the expected effect of the final rule on society by exploring the benefits of the quality and duration improvements on children enrolled in Head Start and their parents and the potential opportunity costs for children who might not have access to Head Start in the future, as well as other unquantified benefits. Further, we discuss the implications of both Congressional and Secretarial actions on the costs and benefits of this rule to society as a whole. Finally, we provide estimates of additional federal funding needed for overtime, adjusted for cost of living increases, to support the full implementation of this rule and we estimate the potential slot loss and education staff job loss that may arise from this rule if the service duration policies described in part 1302, subpart B, are fully implemented without adequate additional funds.

Return on Investment in Early Childhood

There is no question that high-quality early learning programs yield significant benefits to children and society.[178] Early learning programs provide a unique opportunity to intervene and support children's development during a period in which learning and growth is at its most rapid.[179] [180] [181] Early learning programs have short and long term effects on children's math, reading and behavior skills, can reduce grade retention, teen pregnancy, and the need for special education services, and in the long-term can increase lifetime earnings and reduce crime.[182] [183] [184] [185] [186] [187] [188] [189] [190] [191] [192] [193] Numerous evaluations of both small-scale and large-scale early education programs demonstrate that the benefits to children and our society outweigh the financial costs of funding these programs. Studies examining the return on investment for early learning programs find a range of levels for positive returns. For example, the Perry Preschool project, a two-year early learning intervention for children from low-income families, netted approximately 7–10 dollars back for every dollar spent on the program, with a baseline estimate of $8.60.[194] [195] Most of these financial benefits came from later reductions in crime. Evaluations of the Chicago Child-Parent Center program (CPC) also show benefits from medium and long-term positive effects. When CPC participants reach age 21, analyses demonstrates that one and a half years of CPC preschool participation yielded a return for society of $7.10. In comparison to preschool children who did not participate in CPC, the preschool participants had lower rates of special education placement and grade retention and a higher rate of high school completion. They also had lower rates of juvenile arrests and lower arrest rates for a violent offense.[196] A recent analysis by some of the country's premier child development and early intervention experts conclude universal pre-kindergarten returns $3–5 in benefits for every dollar spent.[197] Nobel Prize winning economist James Heckman concludes that educational interventions in the first five years of life show much greater benefits than later interventions.[198]

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Taken together, this research suggests that participation in early learning programs can help support optimal child development, particularly for children from low-income families, with benefits for society lasting well into adulthood. However, early learning programs must be sufficiently high quality to reap these benefits. The congressionally mandated, randomized control trial study of Head Start's impact did not show lasting effects on the outcomes measured beyond the end of the Head Start program years.[199] However, recent reanalysis of data from the Head Start Impact Study suggests that those programs that were high-quality had greater effects on children, providing further confidence in the benefits of participation in high-quality Head Start programs.[200] In addition, based on monitoring data, including Classroom Assessment Scoring System (CLASS), and findings from FACES and the Head Start Impact Study, we also know that there is significant variance in quality among Head Start programs.[201] [202] [203] Further, longer program duration may allow more Head Start parents to work, which would have benefits to Head Start children and to society.[204] [205] In order for Head Start to achieve its mission to be an effective tool in supporting children's success in kindergarten and beyond, and for society to reap the full benefits of this investment, every Head Start program is providing high quality services that will promote strong and lasting child outcomes.

Review of Research on Early Education Duration

The Secretary's Advisory Committee recommended Head Start look to "optimize dosage," and our new requirements will ensure Head Start programs become more aligned with state pre-kindergarten programs that have shown strong effects over time.[206] [207] For example, North Carolina pre-kindergarten, which is offered to lower income families and operates 6.5 hours per day and 180 days per year, demonstrates strong effects. Children who attend the program make gains in language, literacy, math, general knowledge and social skills. At the end of 3rd grade, children from low-income families who had attended state pre-kindergarten scored higher on math assessments than children from low income families who did not attend. Moreover, children who are dual language learners make gains at even faster rates than other children.[208] New Jersey's state pre-kindergarten, which operates between 6–10 hours per day and 180–245 days per year shows significant impacts for child learning. Children who attend New Jersey pre-kindergarten show improvements in language, print awareness, and math at kindergarten entry, 1st grade, and 2nd grade. Gains still exist in language arts, literacy, math, and science at 4th and 5th grade. They also show a 40 percent decrease in grade retention and a 31 percent decrease in special education placement.[209]

Other states with service duration consistent with our minimum annual hours find strong results for children. For example, Georgia pre-kindergarten, which operates 6.5 hours per day and typically runs 180 days per year, finds medium to large effects on children's language, literacy, and math skills at kindergarten entry.[210] Tulsa pre-kindergarten also shows strong effects for children in language and math skills. This program operates 180 days per year and is mainly a full-day program for low-income children. There is some evidence that full-day attendance in Tulsa supports better outcomes for low income and minority children.[211] Boston pre-kindergarten, which also operates for a full school day and school year, demonstrates large effects on children's language and math skills.[212]

Only a small amount of research with young children has been able to isolate the impact of service duration on child learning, but what does exist links increasing the length of the program day and program year to improved children's outcomes. For example, a randomized control study in which one group of children attended pre-kindergarten for 8 hours per day for 45 weeks and another group of children attended the same program for 2.5–3 hours per day for 41 weeks found that by the spring of kindergarten, the children who had attended full-day pre-kindergarten had improved almost twice as much on vocabulary and math skills compared to the children who attended half day.[213] Research with children in child care settings found 30 hours of participation each week to be necessary for low and middle income children to see stronger learning outcomes.[214]

Moreover, research on effective teaching practices for children at risk of school difficulties also support the need for full-day operation. A meta-analysis of pre-kindergarten programs found that those that focused on intentional teaching and small group and one-to-one interactions had larger impacts on

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child outcomes.[215] It is very difficult for a half-day program to provide sufficient time for teachers to conduct learning activities and intentional instruction in small group and one-on-one interactions in the areas of skill development experts believe are important to later school success.

Researchers believe meaningful skill development in language, literacy, and math requires intentional, frequent, and specific methods of instruction and teacher-child interactions. These types of interactions are often complex, require a variety of types of interactions and intensities, and for many children in Head Start, need to be conducted in small groups to allow sufficient individualized scaffolding and skill development.[216] Experts believe math curriculum and instruction must support development of broad and deep mathematical thinking and knowledge, including development of abstract thought and reasoning.[217] Targeted instruction and small group activities are teaching practices that are particularly important to include for supporting the learning of children who are behind.[218][219] Language and literacy experts believe teachers must take an active role in supporting language and literacy development for children at risk of reading difficulties. That requires systematic and explicit instruction to foster vocabulary breadth and depth. Research with toddlers and preschool age children also finds that greater exposure to rich vocabulary enrichment allows for better scaffolding that can lead to improved language and literacy.[220][221] As such, experts recommend in addition to integration into group learning and free play, language and literacy instruction should be explicitly structured and sequenced in 15–20 minutes small group session at least three times per week.[222] Math experts have similar time estimates for supporting adequate high quality learning experiences.[223][224]

Research on summer learning loss demonstrates the importance of extending the minimum days of operation in Head Start. Research on reading skills found high-income students gained skills over summer break, middle-income students maintained their skill level, and children from lower income families lost skills.[225] Experts conclude the average student loses one month worth of skills and development over the summer break.[226] The amount of learning loss is even greater for children from low income families who may not have as much access to educational resources and experiences during the summer and who are already behind their more advantaged peers and need extra time to learn skills and strengthen development.[227][228][229][230][231] This pattern is also true for the youngest children in elementary school. Analysis of the ECLS finds that children from families with higher incomes learn more over the summer between kindergarten and 1st grade than do children from families with lower incomes.[232] In fact, researchers believe the effects of summer learning loss for children from low-income families is cumulative and that the disparity in summer gains and losses over the first four summers of elementary school is greater than the differential between children from high and low income families at school entry.[233] Experts also conclude summer learning loss in elementary school predicts poor academic achievement in high school.[234]

Research on attendance also finds exposure to additional learning time is important for skill development.[235][236] Research with elementary school children has shown an increase in school attendance predicted improved reading scores.[237] A recent study of preschool attendance in Chicago found that even when accounting for children's skill level at the beginning of preschool, attendance predicted better academic outcomes at the end of preschool and beyond and that attendance was most beneficial for children starting preschool with the lowest skills. Children who missed more preschool had lower math, letter recognition, and social-emotional skills and were also rated as lower on work habits by their teachers.[238]

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In sum, providing high-quality early education is not a simple task. Standards must be high to create learning environments that allow teachers to facilitate effective early learning experiences and support must be provided that continuously builds teachers' skills and knowledge. Taken together this research clearly indicates previous Head Start minimums for program operations are inadequate to achieve the results researchers and economists have shown are possible. Although the evidence does not point to a particular threshold for the length of the day or length of the year that is necessary to ensure positive child outcomes, the research is clear that children will benefit from more exposure to early learning experiences than our previous minimums provide.

Costs and Benefits to Society

It is our expectation that this rule will be implemented with sufficient funds to avoid slot loss resulting from costs associated with this rule. In FY 2016, Congress appropriated $294 million specifically to increase service duration for Early Head Start and Head Start programs, which cover some of the costs of the duration requirements in this final rule. The President's FY 2017 Budget includes a request for an additional $292 million. Collectively these funds would allow all programs to increase service duration so that at least 50 percent of their Head Start center-based slots and 100 percent of their Early Head Start center-based slots would meet the respective new minimums of 1,020 and 1,380 annual hours by August 1, 2018, as required in this rule. Congress would need to appropriate additional funds to support the full implementation of the Head Start center-based service duration requirement by February 1, 2020, the date by which the Secretary will decide whether to lower the percentage of slots required to increase duration based on an assessment of the availability of sufficient appropriations to mitigate substantial slot loss. If fully funded, this rule would result in a significant increase in the quality of Head Start and the associated benefits of Head Start participation for all children. Ample research, also discussed above, demonstrates the potential for early education programs to produce large returns on investment to society through benefits associated with short and long term effects on children's math, reading and behavior skills; reduced grade retention, teen pregnancy, need for special education services, crime, and delinquency; and increased lifetime earnings.[239] [240] [241] [242] [243] [244] [245] [246] [247] [248] [249] [250] This research, coupled with research indicating the importance of adequate duration in early learning programs, would suggest that extending program duration and increasing program quality will result in additional benefits for any child enrolled in a Head Start program that does not already meet or exceed the bar set for program quality in this rule. The relative size of these additional benefits will likely vary from program to program and it is not possible for this analysis to quantify the precise benefit. Additionally, if the rule is fully implemented with adequate funding, there may be benefits associated with additional teacher jobs, higher staff salaries, and increased support for parental work. Finally, this rule increases clarity of Head Start requirements which should lead to greater compliance, which should in turn, result in improved child safety and stronger child and family outcomes. However, it is also not possible for this analysis to quantify these benefits.

If the Secretary exercises this authority, the final rule would result in a smaller benefit to society than the fully funded rule, because fewer children would benefit from greater exposure to high-quality early learning experiences. However, if the Secretary does not exercise this authority, this rule could result in a decrease of as many as 123,000 slots, depending upon appropriations and whether programs are able to absorb any costs of the rule within their current operating budgets. This slot loss has costs to society because fewer children will have access to Head Start in the future; although these costs have been estimated in preceding portions of this regulatory impact analysis, the quantification does not account for the relative size of these potential costs, which likely vary from program to program and from child to child (perhaps most notably in the form of diminishing returns to Head Start exposure). Additionally, if the rule is fully implemented without adequate funding, there may be costs associated with job loss, however it is not possible for this analysis to quantify them.

Further, this cost to society may be mitigated by the availability of other early learning programs, given findings from the Head Start Impact Study that indicate a wide range of early childhood education utilization among children who do not have access to Head Start.[251] In this case, determining how the loss of slots impacts society depends on how benefits differ between Head Start and the alternative early childhood education programs. Among children whose future Head Start slots are eliminated, children who enroll in alternative early childhood education programs of similar quality would not experience a loss of benefits, while children who enroll in programs of lower quality or no program at all would experience lost benefits. To be sure, quality and affordable early learning programs for poor families are limited and there is significant unmet need. A

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reduction in Head Start slots may is unlikely to not be fully absorbed by other programs given that other early learning programs are not universally available to all children and these programs only currently serve a fraction of the eligible population. The total benefit to society of the rule would depend upon the relative size of the benefits to children who receive greater exposure to high-quality early learning experiences compared to the lost benefits for children who no longer have access to Head Start.

Continuing to operate under widely varying minimums for program duration, in the face of the mounting evidence provided here, limits Head Start's overall effectiveness and undermines Head Start's mission. This rule is designed to ensure every child in Head Start receives the highest quality program. The requirements to extend program duration are inextricably linked to reaping the full range of benefits that researchers and economists have demonstrated are possible.

Implications of Congressional and Secretarial Actions

The costs of this rule vary over the next ten years of implementation based upon compliance dates and staff turnover. In FY 2016, Congress appropriated $294 million to pay for programs to increase service duration. As a result and as explained throughout this analysis, the costs associated with increasing the service duration requirements in this rule are reduced. Further, the President's FY 2017 Budget requests an additional $292 million to further support quality improvements. If Congress provides additional resources in FY 2017 and beyond, the costs associated with this rule would be borne, in part or whole, by the federal government rather than by Head Start programs. In this scenario, there may not be any slot loss associated with the requirements in this rule. Rather, the full additional potential benefits of higher quality services would be realized for all children who attend Head Start.

In the table below, we have estimated the amounts Congress would need to appropriate in order to support the full implementation of the requirements to increase Head Start center-based program duration. Note that we have assumed Early Head Start center-based duration will be fully funded using the FY 2016 appropriation for expansion of program duration. In order to capture the full cost of the Head Start center-based requirements over time, we have adjusted the necessary funding levels to account for cost of living increases as forecasted in the OMB Economic Assumptions for MSR. As the table demonstrates, in order to fully support the requirements to increase program duration, Congress would need to appropriate $264 million in FY 2018 or earlier to support the 50% requirement and an additional $711 million in FY 2020 or earlier to support the 100% requirement.

	Appropriation year	Effective date	Secretarial determination date	Cost of policy (less the FY16 appropriation), before adjustment for COLAs (million)	Appropriation needed, adjusted for COLAs (in addition to FY16 appropriation) (million)	Additional appropriation, adjusted for COLAs (if $264 received by FY2018) (million)
50% Requirement for HS CB programs.	Fiscal Year 2018	August 1, 2019	February 1, 2018	$245	$264	
100% Requirement for HS CB programs.	Fiscal Year 2020	August 1, 2021	February 1, 2020	866	975	$711

If Congress does not appropriate adequate funds, § 1302.21(c)(3) of the final rule gives the Secretary the authority to reduce the requirements for service duration based on an assessment of what available funds can support. In this scenario, as in the scenario where adequate funds are appropriated, there would be no slot or teacher job loss associated with the duration requirements in this rule.

However, if the Secretary does not exercise this authority, the duration requirements in this rule could result in a decrease of as many as 107,762 slots slots (full estimate described below), depending upon appropriations and whether programs are able to absorb any costs of the rule within their current operating budgets. This slot loss has costs to society because fewer children will have access to Head Start in the future. The total benefit to society of the rule would depend upon the relative size of the benefits to children who receive greater exposure to high-quality early learning experiences compared to the lost benefits for children who no longer have access to Head Start. Both Congressional and Secretarial decisions have important implications for the number of children served by the program and the characteristics of the program.

Although we are unable to quantify the associated costs and benefits that would arise from these implementation scenarios, it is important to keep these factors in mind as we consider both the societal costs and savings and the cost-benefit analysis of this final rule.

Potential Slot Loss

In order to estimate slot loss as programs adjust their budgets in the absence of additional funding, we first determined the proportion of current funded enrollment that are Head Start slots (83.8 percent) and Early Head Start slots (16.2 percent), respectively. We then applied this proportion to the total monetary cost associated with this rule, in each out-year, in FY 2016 dollars, and divided the cost that would be borne in Head Start slots by the average cost per slot for Head Start in FY 2015 ($8,035) and the cost that will be borne in Early Head Start by the average cost per slot for Early Head Start in FY 2015 ($12,189), which is inclusive of the cost per child for Early Head Start-Child Care Partnerships. We use FY 2015 average costs because it is the most recent year for which we have final data. In this case, we did not inflate the Head Start cost per child to incorporate teacher salary increases or additional service hours because we believe the current cost per child is the best indicator for the number of slots programs would need to cut to absorb new costs. We also assumed that the additional $294 million appropriated in FY 2016 will fully fund Early Head Start duration ($30,878,060) and support some proportion of all Head Start grantees slots serving children for 1,020 hours.

Without additional funding, the net costs of this rule borne by Head Start, if fully implemented could be associated with a reduction in slots (number of children served) of as many as 123,614 by year ten. However, it is important to note that we believe these are overestimates of the actual potential slot loss, because many of the costs estimated in this section, aside from the increases in duration, represent changes in how programs will use existing funds rather than additional new costs that would result in slot loss. As stated earlier, this slot loss would not occur if the Secretary exercises discretion provided in the rule to reduce the duration requirements or if sufficient appropriations are provided by Congress to support the policy. This would also be an overestimate if Congress appropriates additional funds to support the full implementation of this rule or if the Secretary exercises the authority to reduce the service duration requirements.

The table below describes the share of costs in years one through ten borne by Head Start and Early Head Start programs and the potential slot loss associated with those costs in each year. Costs vary by year based upon effective dates of individual provisions and whether those costs are one-time or ongoing.

POTENTIAL SLOT LOSS

[If Congress does not appropriate sufficient funding in future years and the Secretary does not use the discretion provided in the Final Rule to lower the duration requirements]

	Year 1 2016/2017 *	Year 2 2017/2018 *	Year 3 2018/2019 *	Year 4 2019/2020 *	Year 5 2020/2021 *
Share of Costs, *Including FY 2016 Funding Appropriated for Duration Increases*					
HS	$0	$105,964,210	$188,593,130	$350,403,218	$455,190,660
EHS	0	28,673,236	44,646,846	28,503,144	48,760,382
Potential Slot Loss					
HS	0	13,188	23,471	43,610	56,651
EHS	0	2,352	3,663	2,338	4,000
Total	0	15,540	27,134	45,948	60,651

	Year 6 2021/2022 *	Year 7 2022/2023 *	Year 8 2023/2024 *	Year 9 2024/2025 *	Year 10 2025/2026 *
Share of Costs *Including FY 2016 Funding Appropriated for Duration Increases*					
HS	$971,741,327	$972,486,346	$973,835,238	$974,263,621	$974,050,651
EHS	28,655,562	28,799,587	29,060,351	29,143,165	29,101,994
Potential Slot Loss					
HS	120,939	121,031	121,199	121,252	121,226
EHS	2,351	2,363	2,384	2,391	2,388
Total	123,289	123,394	123,583	123,643	123,614

* Year ranges refer Head Start program years, which for these estimates, begin on August 1st of each year and end on or before July 31st.

** The costs and slot loss estimates in this table take into account the $294 million appropriated for increased duration, and assume that this funding is applied beginning in Year 3 for Early Head Start and Year 4 for Head Start, when the initial duration requirement would be effective, and is maintained throughout the ten year window. This table also assumes that the share of HS and EHS slots is stable over time.

Potential Education Staff Job Loss

In order to estimate the total potential number of education staff jobs that may be lost if a slot reduction occurs as a result of full policy implementation without additional funding, we first reduced the costs of the rule borne by Head Start by the cost of eliminating the option for double sessions for Head Start and Early Head Start. Double session programs typically have the same teacher operate a morning and afternoon session with different groups of children. Therefore, we assume double session teachers would not lose their jobs, even if fewer children are served in those programs because they would teach one group of children for a longer session. We also assumed that the additional $294 million appropriated in FY 2016 will fully fund Early Head Start center-based duration increase (estimated at $30,878,060). To determine the costs borne by Head Start (not including duration) that may be associated with education staff job loss for Early Head Start, we subtracted center-based duration costs from the total costs borne by Early Head Start programs ($59,980,054), which is $29,101,994.

In order to estimate the education staff job loss for Head Start that would be associated with costs borne by Head Start programs, we assumed that an equal distribution of double session and non-double session Head Start center-based slots will be increased using supplemental duration funds out of the FY 2016 appropriation of $294 million which will support all grantees providing 1,020 hours for at least one-third of their slots. Based on this assumption, we divided the $263,121,940 appropriated in FY 2016 for duration (less the cost of the Early Head Start center-based duration increase) by two, which is $131,560,970. We then subtracted the $131,560,970 from the non-double session Head Start share of the total costs ($652,809,539) to find the cost of non-double session slots not supported by FY 2016 appropriations, which is $521,248,569. Then, we divided the $521,248,569 for Head Start by the average cost per child for Head Start, or $8,035, and the non-duration costs for Early Head Start ($29,101,994) by the average cost per slot for Early Head Start, or $12,189, to find the number of slots in Head Start (64,872) and Early Head Start (2,388) associated with these costs.

Then, to account for education staff to child ratios and caseloads that differ by the program option and the age of the child, we applied current percentages from the Program Information Report (PIR) for the proportion of Head Start slots that are center-based, home-based, and other program options (including family child care, locally designed, and combination programs), which are 96 percent, 2.2 percent, and 1.8 percent respectively. These proportions result in 62,277 Head Start center-based slots, 1,427 home-based, and 1,168 other program option slots, assuming programs would reduce center-based, home-based, and other program options proportionately in the face of insufficient funds. Finally, we applied the proportion of three- versus four-year olds in Head Start from the PIR to find 27,679 three-year-old and 34,599 four-year old center-based slots.

We also applied the proportion of Early Head Start slots that are center-based, home-based/pregnant women, and other program options (including family child care, locally designed, and combination programs), 47 percent, 48 percent, and 5 percent respectively, to calculate that there would be 1,122 Early Head Start center-based slots, 1,146 home-based/pregnant women slots, and 119 other program option slots, assuming programs would reduce center-based, home-based/pregnant women, and other program options proportionately in the face of insufficient funds. Finally, we applied the appropriate education staff to child ratios and caseloads for center-based program options by age, home-based, other program options to determine the total number of Head Start and Early Head Start education staff jobs that would potentially be lost.

If fully implemented without additional funding, this rule could result in a reduction of as many as 7,372 education staff jobs by year ten.

4. Accounting Statement—Table of Quantified Costs, and Transfers

As required by the Office of Management and Budget (OMB) Circular A–4, we have prepared an accounting statement table showing the classification of the impacts associated with implementation of this final rule. We decided to use a 10-year window for this regulatory impact analysis. As required by OMB, we discount costs at 3 percent and 7 percent and have included total present value as well as annualized value of these estimates in our analyses below.

We also include costs borne by other parties, opportunity costs and cost transfer, separate from costs borne by Head Start, here, because they impact the total cost to society of the rule.

SUMMARY OF COSTS AND DISCOUNTING

[In millions]

	Year 1 2016/2017	Year 2 2017/2018	Year 3 2018/2019	Year 4 2019/2020	Year 5 2020/2021
Costs Borne by Head Start, *excluding duration funding appropriated beginning in FY 2016*	$(46)	$135	$264	$673	$798
Net Costs Borne by Head Start, *including duration funding appropriated beginning in FY 2016*	(46)	135	264	379	504
Costs Borne by Other Parties	42	45	44	44	45
Opportunity Costs	0.5	4	4	4	4
Costs to Society (Undiscounted), *excluding duration funding appropriated beginning in FY 2016*	(3)	183	312	721	847
3% Discount	(3)	178	294	660	752
7% Discount	(3)	171	272	589	646
Costs to Society (Undiscounted), *including duration funding appropriated beginning in FY 2016*	(3)	183	312	427	553
3% Discount	(3)	178	294	391	491
7% Discount	(3)	171	272	349	422
	Year 6 2021/2022	Year 7 2022/2023	Year 8 2023/2024	Year 9 2024/2025	Year 10 2025/2026
Costs Borne by Head Start, *excluding duration funding appropriated beginning in FY 2016*	$1,294	$1,295	$1,297	$1,297	$1,297
Net Costs Borne by Head Start, *including duration funding appropriated beginning in FY 2016*	1,000	1,001	1,003	1,003	1,003
Costs Borne by Other Parties	45	46	46	47	46
Opportunity Costs	4	4	4	4	4
Cost to Society (Undiscounted), *excluding duration funding appropriated beginning in FY 2016*	1,344	1,345	1,347	1,348	1,348
3% Discount	1,159	1,126	1,095	1,064	1,033
7% Discount	958	896	839	784	733
Costs to Society (Undiscounted), *including duration funding appropriated beginning in FY 2016*	1,050	1,051	1,053	1,053	1,053
3% Discount	905	880	856	832	808
7% Discount	748	700	656	613	573

* Year ranges refer Head Start program years, which for these estimates, begin on August 1st of each year and end on or before July 31st.

** Note these costs do not include the potential lost benefits of children who may no longer have access to Head Start or the impact on children who attend other early education programs.

In total, we estimate the 10-year present value of the costs associated with new requirements in this final rule to be $7,358 million when discounted at 3 percent, and $5,886 million when discounted at 7 percent before accounting for the $294 million in funding Congress has provided in FY 2016 to expand duration. We estimate the annualized costs of new requirements in this final rule to be $838 million when discounted at 3 percent, and $783 million when discounted at 7 percent before accounting for the $294 million in funding Congress has provided in FY 2016 to expand duration. As noted, Congress appropriated $294 million in FY 2016 to increase the duration of Early Head Start and Head Start programs. Thus, a substantial share of the costs in this rule will be absorbed by this funding. Accounting for the funding Congress has already provided in FY 2016 to increase duration, we estimate the 10-year present value of the costs to be $5,632 million when discounted at 3 percent, and $4,502 when discounted at 7 percent. The annualized costs of new requirements in this final rule, when taking into these amounts already appropriated for duration, would be $641 million when discounted at 3 percent and $599 million when discounted at 7 percent.

COSTS TO SOCIETY DISCOUNTED AND ANNUALIZED

[In millions]

	Annualized (years 1–10)		10 year total	
	Discounted 3%	Discounted 7%	Discounted 3%	Discounted 7%
Cost to Society, *excluding duration funding appropriated beginning in FY 2016*	$838	$783	$7,358	$5,886
Cost to Society, *including duration funding appropriated beginning in FY 2016*	641	599	5,632	4,502

5. Distributional Effects

As part of our regulatory analysis, we considered whether the final rule will disproportionately benefit or harm a particular subpopulation. If adequate funds are not appropriated, the final rule has the potential to result in a reduction in the number of children being served by Head Start and an improvement in quality for the much larger group of low-income children who continue to participate. We do not expect the children who may lose access to Head Start if the funding is not provided to be systematically different in terms of meaningful subpopulations from the children who will be receiving greater benefits from higher quality services. We also acknowledge that if adequate funds are not appropriated, as many as 7,372 teachers, assistant teachers, and home visitors could no longer be employed. Again, while these teachers would be economically harmed, the remaining 110,933 teachers, assistant teachers, and home visitors whose employment is not terminated, should receive pay increases because of working longer hours and longer program years. We do not expect the teachers who are no longer employed to be systematically different in terms of meaningful subpopulations from the teachers who will see increased pay because of this rule.

We also considered whether there would be a differential impact of the final rule, specifically the requirements to increase duration, on either children or teachers based upon geographic location or tribal affiliation. While we found significant variation at the state level with regard to the proportion of slots that provide 1,020 annual hours in Head Start and 1,380 annual hours in Early Head Start, there are no systematic differences based on the region of the country (*e.g.,* North vs. South; Midwest vs. West, etc.). Further, if the rule is fully implemented, some children in every state will benefit from increased duration. We also found no systematic differences between tribal programs and non-tribal programs with regard to meeting the new minimums.

6. Regulatory Alternatives

As part of our full regulatory analysis, we have considered several regulatory alternatives, which we outline below. Specifically, we have considered alternatives to the policy changes we have determined to be our largest cost-drivers: Extension of Head Start center-based program duration and mentor coaching. We consider alternatives to these policy changes by analyzing the effect of the net cost in dollars, slots, and education staff jobs of making no change to the existing rule, as well as other more costly policy changes. In fact, the requirements in this rule for Head Start center-based duration represent an alternative to the requirements proposed in the NPRM. Justifications for the policies set by this rule are embedded throughout the discussion of comments received. However, we do provide additional rationale for not opting to propose or finalize the more costly regulatory alternatives in this section.

Extension of Head Start Center-Based Program Duration

The rule requires Head Start center-based programs to provide a minimum of 1,020 annual hours for all children by August 1, 2021, but gives the Secretary authority to reduce this requirement to mitigate slot loss from the duration requirements in the event that Congress does not appropriate adequate funds to support the policy. As described in great detail above, these requirements will increase the amount of instructional time in Head Start programs, which research suggests is critical to reaping the full benefits of the other quality improvements in the rule.[252] [253] In our cost analysis, we estimated the cost of the Head Start center-based duration requirement, if fully implemented to be $1,128,990,485. Once the expected proportion of the FY 2016 appropriation to increase program duration in Head Start is applied, the cost of these requirements is $865,868,544. These requirements are associated with a potential loss of between 0 and 107,762 slots and between 0 and 5,475 education staff jobs, depending upon appropriations and Secretarial action. As part of our full regulatory analysis, we considered three alternatives to this policy change.

First, we considered the alternative of making no change to our previous minimums, thus eliminating the associated cost of $865,868,544. Using the methodology enumerated above, making no change to this policy would be associated with up to 107,762 fewer slots lost and 5,475 fewer education staff no longer employed. However, not making this change would also prevent the significant predicted increase in impacts on child outcomes we have described in the Benefits Analysis section. We believe that strong child outcomes are best fostered through high-quality early education programs that provide at least a full school day and full school year of services and that children are best served if Head Start programs continue to move toward this goal and there is ample research that points to increased duration in achieving positive child outcomes.[254] [255] [256] [257] [258] [259] [260] [261] [262] [263] [264] Therefore we have not included this alternative in the final rule.

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[252] Weiland, C., & Yoshikawa, H. (2013). Impacts of a prekindergarten program on children's mathematics, language, literacy, executive function, and emotional skills. *Child Development, 84,* 2112–2130.

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We also considered the alternative proposed in the NPRM to extend the minimum Head Start year to 180 days and the Head Start day to 6 hours. Using the same method employed in our original cost analysis in the NPRM, We updated the original cost analysis by using 2015 data, inflating for missing GABI data, and inflating by 20% to reflect changes made to the final rule cost estimate in response to comments that account for fringe benefits and remove the assumption that additional administrative costs will not be necessary to support increased duration). These changes provide comparable estimates for weighing the potential impacts of regulatory alternatives. Using this method, the total costs of this alternative (NPRM proposal) would be $ 1,308,629,691. Once the expected proportion of the FY 2016 appropriation to increase program duration in Head Start is applied, the cost of these requirements is $1,045,507,751. These costs would result in a total of 130,119 slots lost and 10,392 education staff no longer employed as a result of this provision alone. The additional associated costs of this alternative, compared to the requirements in the final rule, would be $179,639,207, which would result in as many as 22,357 additional slots lost and 4,917 additional education staff no longer employed.

Again, research clearly demonstrates that strong child outcomes are best fostered through high-quality early education programs that provide at least a full school day and full school year of services, however, research does not specify a threshold for this effect.[265] [266] [267] [268] [269] [270] [271] [272] [273] [274] [275] Given this, we believe it is important to allow programs to design a variety of different schedules within the minimum requirements that meet the specific needs of their families, communities, and staff. We believe the flexibility of the annual hours, rather than the specified hours per day and days per year of this regulatory alternative will allow programs to address many of the concerns that were raised in the comments, such as alignment of the summer break with the local education agency's calendar, the availability of facilities, the continuation of partnerships, and state licensing requirements.

Finally, we considered the alternative of requiring Head Start center-based programs to provide a minimum of 1,020 annual hours for all children by August 1, 2021, but not giving the Secretary authority to reduce this requirement to mitigate slot loss in the event that adequate funds to support the policy are not appropriated. This policy would guarantee, in the event that Congress does not appropriate adequate funds to support the policy, at least some children would lose access to Head Start and some education staff would no longer be employed by Head Start.

However, the negative effects of implementing this model in such a way that could lead to significant reductions in the number of children and families served by Head Start programs, may outweigh the benefits. Therefore, we specify an incremental timeline and process for grantees to shift their programs to provide at least a full school day and a full school year of services to all preschoolers in center-based settings, which will allow programs to extend their service duration models thoughtfully. Further, we gave the Secretary the discretion to lower the required percentage of funded enrollment slots for which grantees must offer 1,020 annual hours of planned class operations to the percentage the Secretary estimates available appropriations can support. This balances the important policy goal of providing all preschoolers with a full school day and a full school year of services in Head Start with the disruption and potential slot loss such a policy might create in the absence of sufficient funding in a way that this regulatory alternative would not.

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We believe the policy set by this final rule represents a balance between empowering Head Start programs to ensure all Head Start children receive enough high quality early learning experiences to improve their outcomes, and ensuring as many children from low-income families as possible are served by Head Start.

REGULATORY ALTERNATIVES: HEAD START CENTER-BASED DURATION

	Status quo	NPRM proposal *	100% to 1,020 for Head Start Center-based without Sec. authority	Final rule
Costs Borne by Head Start, excluding FY 2016 duration funding	0	$1,308,629,691	$1,128,990,485	$1,128,990,485
Costs Borne by Head Start, including FY 2016 duration funding		1,045,507,751	865,868,544	865,868,544
Slot Loss	0	130,119	107,762	0–107,762
Job Loss	0	10,392	5,475	0–5,475

* Note the NPRM proposal cost estimate has been inflated to reflect changes made to the final rule cost estimate that account for fringe benefits and remove the assumption that additional administrative costs will not be necessary to support increased duration.

Mentor Coaching

In this rule, we require programs to have a system of professional development in place that includes an intensive coaching strategy. As with our other largest cost drivers, as part of our full regulatory analysis, we considered two alternatives to this policy change. Specifically, we considered the alternative of not requiring mentor coaches for any teaching staff, thus eliminating the associated cost of $141,978,651. This alternative would be associated with 16,694 fewer slots potentially lost and 1,902 fewer educations staff potentially no longer employed. However, a growing body of research demonstrates the effectiveness of intensive professional development for improving teacher practices in early care and education settings[276] [277] [278] and that such strategies support improved teacher practice in the classroom and an increase in classroom quality.[279] [280] This alternative would not allow children to reap the benefits of higher quality early learning programs, through improved teaching practices.

We also considered the alternative of requiring mentor coaches for all teaching staff, rather than allowing programs to allocate mentor coaches to the teachers who need intensive professional development, most (an estimated one-third of all teaching staff). Using the same method employed in our original cost analysis, the additional associated costs of this alternative would be $425,935,952 total or $283,957,301 more than our final policy, which would result in 50,083 total or 33,389 additional slots potentially lost and 5,707 total or 3,805 additional education staff potentially no longer employed. As described in previous sections, we strongly believe that more intensive, focused professional development is critical to improving teaching quality and thereby increasing impacts on child outcomes. However, we believe it would be inefficient to mandate that every teacher receive intensive individualized coaching when local professional development needs may need to be met.

Our requirement will achieve our goal of improving teacher practices by targeting teachers most in need of coaching to improve their teaching practices while still maintaining local flexibility for individualized professional development.

REGULATORY ALTERNATIVES: MENTOR COACHING

	Status quo (no coaching)	Coaching for all teachers	Final rule (coaching for one-third of teachers)
Cost	0	$425,935,952	$141,978,651
Potential slot loss	0	50,083	16,694
Potential job loss	0	5,707	1,902

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The Unfunded Mandates Reform Act (UMRA)[281] was enacted to avoid imposing unfunded federal mandates on state, local, and tribal governments, or on the private sector. Most of UMRA's provisions apply to proposed and final rules for which a general notice of proposed rulemaking was published, and that include a federal mandate that may result in expenditures by state, local, or tribal governments, in the aggregate, or by the private sector of $100 million or more (adjusted annually for inflation) in any one year. The current threshold after adjustment for inflation is $146 million, using the most current (2015) implicit price deflator for the gross domestic product. This final rule does not impose unfunded mandates on state, local, and tribal governments, or on the private sector.

d. Treasury and General Government Appropriations Act of 1999

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires federal agencies to determine whether a policy or regulation may negatively affect family well-being. If the agency determines a policy or regulation negatively affects family well-being, then the agency must prepare an impact assessment addressing seven criteria specified in the law. This rule does not have any impact on the autonomy or integrity of the family as an institution. Accordingly, we concluded it was not necessary to prepare a family policymaking assessment.[282]

e. Federalism Assessment Executive Order 13132

Executive Order 13132 requires federal agencies to consult with state and local government officials if they develop regulatory policies with federalism implications. Federalism is rooted in the belief that issues that are not national in scope or significance are most appropriately addressed by the level of government close to the people. This final rule does not have substantial direct impact on the states, on the relationship between the federal government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

f. Congressional Review

The Congressional Review Act (CRA) allows Congress to review "major" rules issued by federal agencies before the rules take effect.[283] The CRA defines a major rule as one that has resulted or is likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, federal, state or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.[284] This regulation is a major rule because it will likely result in an annual effect of more than $100 million on the economy.

g. Paperwork Reduction Act of 1995

The Paperwork Reduction Act of 1995 (PRA), P.L. 104–13, minimizes government imposed burden on the public. In keeping with the notion that government information is a valuable asset, it also is intended to improve the practical utility, quality, and clarity of information collected, maintained, and disclosed.

Regulations at 5 CFR part 1320 implemented the provisions of the PRA and § 1320.3 of this part defines a "collection of information," "information," and "burden." A "collection of information" is broadly defined and includes any requirement or request for persons to collect, maintain, or publicly disclose information. "Information" is defined in as any statement or estimate of fact or opinion, regardless of form or format, whether numerical, graphic, or narrative form, and whether oral or maintained on paper, electronic or other media. "Burden" means the total time, effort, or financial resources expended by persons to collect, maintain, or disclose information. Burden includes actions for the purposes of information request such as reviewing instructions, acquiring and using technology and systems, adjusting the existing ways to comply with any previously applicable instructions and requirements, completing and reviewing the collection of information, and transmitting the information. The PRA only counts as burden the net additional burden needed to comply with information request. Time, effort, and resources to collect information that would be incurred by persons in the normal course of their activities are excluded from the burden.

Section 1320.11(f) of 5 CFR part 1320 requires an agency to explain in the final rule how information collections proposed in an NPRM respond to any comments received or the reasons such comments were rejected. We did not receive any comments directly related to information collections we proposed in the NPRM. Therefore, we did not make any changes here.

Below, we describe information collections and their burden estimates:

Title: Head Start Grants Administration

Description: We require information collections related to the protection for the privacy of child records. We require programs to collect parents' written consent before they disclose personally identifiable information from a child's records. We require programs to notify parents annually of their rights described in §§ 1303.20 through 1303.24 and of applicable definitions in part 1305. We also require programs to maintain, with each child record, information on all individuals, agencies, or organizations that have obtained access to personal identifiable information from child records.

Title: Head Start Performance Standards

Description: We require a new information collection to codify best practice in assessing dual language learners. Specifically, we require programs to administer language assessments to dual language learners in both English and their home language, either directly or through interpreters.

We also strengthen background check procedures to require state/tribal or federal criminal background checks, as well as clearance through available child abuse and neglect and sex offender registries. This requirement is consistent with the Office of Child Care's requirement to minimize burden on programs that operate with both Head Start and Child Care Development Funds. This increases the record-keeping burden related to criminal record checks.

Description of Respondents and Burden Estimate: The total annual burden hours estimated is 1,019,473 hours. For some items, we calculated burden hours for individual children and families, for other items, we calculated burden hours for staff.

The table below lists burden hour estimates and indicates our bases for these estimations. See the Regulatory

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[281] 2 U.S.C. 1501 *et seq.*

[282] Public Law 105–277.

[283] 5 U.S.C. 802(a).

[284] 5 U.S.C. Chapter 8.

Impact Analysis section for cost estimations.

Information collection	OMB Control No.	Number of respondents	Number of responses per respondent	Average burden per response	Total burden hours
Annual Reporting Burden Estimates					
N/A	N/A	N/A	N/A	N/A	N/A
Annual Recording Keeping Burden Estimates					
Head Start Grants Administration: § 1303.22, 1303.24 Parental Consent, Annual Notice, and Recordkeeping of PII Disclosure.	0970–0423	988,923 (F)	1	20 minutes	329,641
Head Start Performance Standards: § 1302.33 Language Assessments of Dual Language Learners.	0970–0148	332,651 (C)	1	2 hours	665,302
Head Start Performance Standards: § 1302.90 Background Checks	0970–0148	73,591 (S)	1	20 minutes	24,530
Annual Third-Party Disclosure Burden Estimates					
N/A	N/A	N/A	N/A	N/A	N/A
Total Burden Hours					1,019,473

Key: C = Children, F = Families, S = Staff.

For informational purposes, currently approved collections of information that will no longer be required are described below:

- *Head Start Grants Administration.* This rule removed certain requirements for grantee agencies including the submission of audits, accounting systems certifications, and provisions applicable to personnel management.
- *Appeal Procedures for Head Start. Grantees and Current or Prospective Delegate Agencies*—This rule removed the appeal procedures by delegate agencies that came from denials or failure to act by grantees. It also removed the appeal procedures by a grantee of a suspension continuing for more than 30 days.
- *Head Start Program Performance Standards.* Numerous record-keeping requirements were removed which will result in a decrease in burden, *i.e.* documentation of the level of effort undertaken to establish community partnerships, written records of roles and responsibilities for each governing body members, the annual written and approval of plans for implementation services for each program area, provisions applicable to personnel management, and record-keeping and sharing of a set of community services and resources.
- *Purchase, Construction and Major Renovation of Head Start Facilities.* We removed some requirements that involved collection of information that will result in a reduction in burden, including the submission of drawings and specifications, costs related to installation of modular unit, statement of procurement procedure for modular units, and obtaining an independent analysis of the cost comparison.

Tribal Consultation Statement

The Office of Head Start conducts an average of 5 Tribal Consultations each year for those tribes operating Head Start and Early Head Start. The consultations are held in geographic areas across the country—Southwest, Northwest, Midwest (Northern and Southern), and Eastern. The consultations are often held in conjunction with other tribal meetings or conferences, to ensure the opportunity for most of the 150 tribes served through OHS to be able to attend, and voice their concerns and issues for their HS/EHS programs. A report is completed after each consultation, and then a final report is compiled and submitted to the Secretary at the end of the year, summarizing the consultations. For the past several years, the primary issues raised have been around Head Start requirements which are the subject of this regulation and ensuring tribes have sufficient funding to meet those requirements. Language and culture are also a primary topic, particularly Head Start supporting efforts to preserve and revitalize language within each tribe, which is specifically addressed in this final rule. Teacher credentials, and, Monitoring, and fiscal issues were also common themes across the consultations, which have allowed us to gather valuable information that informed the development of this rule. Through the notice and comment process we also received comments from tribal communities, including form the National Indian Head Start Directors Association which informed the development of this final rule.

List of Subjects

45 CFR Part 1301

Education of disadvantaged.

45 CFR Part 1302

Education of disadvantaged, Grant programs—social programs, Homeless, Immunization, Migrant labor, Individuals with disabilities, Reporting and recordkeeping requirements, Indians, Health care, Oral health, Mental health programs, Nutrition, Safety, Maternal and child health, Volunteers.

45 CFR Part 1303

Administrative practice and procedure, Education of disadvantaged, Grant programs—social programs, Reporting and recordkeeping requirements, Privacy, Real property, acquisition, Individuals with disabilities, Transportation, Motor vehicles.

45 CFR Part 1304

Education of disadvantaged, Grant programs—social programs, Designation renewal system, Scholarships and fellowships, Indians.

45 CFR Part 1305

Definitions.

Approved: June 10, 2016.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

Sylvia M. Burwell,

Secretary.

For the reasons set forth in the preamble, under the authority at 42 U.S.C. 9801 *et seq.*, subchapter B of 45 CFR chapter XIII is revised to read as follows:

SUBCHAPTER B—THE ADMINISTRATION FOR CHILDREN AND FAMILIES, HEAD START PROGRAM

PART 1300—[Reserved]

PART 1301—PROGRAM GOVERNANCE

PART 1302—PROGRAM OPERATIONS

PART 1303—FINANCIAL AND ADMINISTRATIVE REQUIREMENTS

PART 1304—FEDERAL ADMINISTRATIVE PROCEDURES

PART 1305—DEFINITIONS

PART 1300—[Reserved]

PART 1301—PROGRAM GOVERNANCE

Sec.
1301.1 Purpose.
1301.2 Governing body.
1301.3 Policy council and policy committee.
1301.4 Parent committees.
1301.5 Training.
1301.6 Impasse procedures.

Authority: 42 U.S.C. 9801 *et seq.*

§ 1301.1 In general.

An agency, as defined in part 1305 of this chapter, must establish and maintain a formal structure for program governance that includes a governing body, a policy council at the agency level and policy committee at the delegate level, and a parent committee. Governing bodies have a legal and fiscal responsibility to administer and oversee the agency's Head Start and Early Head Start programs. Policy councils are responsible for the direction of the agency's Head Start and Early Head Start programs.

§ 1301.2 Governing body.

(a) *Composition.* The composition of a governing body must be in accordance with the requirements specified at section 642(c)(1)(B) of the Act, except where specific exceptions are authorized in the case of public entities at section 642(c)(1)(D) of the Act. Agencies must ensure members of the governing body do not have a conflict of interest, pursuant to section 642(c)(1)(C) of the Act.

(b) *Duties and responsibilities.* (1) The governing body is responsible for activities specified at section 642(c)(1)(E) of the Act.

(2) The governing body must use ongoing monitoring results, data on school readiness goals, other information described in § 1302.102, and information described at section 642(d)(2) of the Act to conduct its responsibilities.

(c) *Advisory committees.* (1) A governing body may establish advisory committees as it deems necessary for effective governance and improvement of the program.

(2) If a governing body establishes an advisory committee to oversee key responsibilities related to program governance, it must:

(i) Establish the structure, communication, and oversight in such a way that the governing body continues to maintain its legal and fiscal responsibility for the Head Start agency; and,

(ii) Notify the responsible HHS official of its intent to establish such an advisory committee.

§ 1301.3 Policy council and policy committee.

(a) *Establishing policy councils and policy committees.* Each agency must establish and maintain a policy council responsible for the direction of the Head Start program at the agency level, and a policy committee at the delegate level. If an agency delegates operational responsibility for the entire Head Start or Early Head Start program to one delegate agency, the policy council and policy committee may be the same body.

(b) *Composition.* (1) A program must establish a policy council in accordance with section 642(c)(2)(B) of the Act, or a policy committee at the delegate level in accordance with section 642(c)(3) of the Act, as early in the program year as possible. Parents of children currently enrolled in each program option must be proportionately represented on the policy council and on the policy committee at the delegate level.

(2) The program must ensure members of the policy council, and of the policy committee at the delegate level, do not have a conflict of interest pursuant to sections 642(c)(2)(C) and 642(c)(3)(B) of the Act. Staff may not serve on the policy council or policy committee at the delegate level except parents who occasionally substitute as staff. In the case of tribal grantees, this exclusion applies only to tribal staff who work in areas directly related to or which directly impact administrative, fiscal, or programmatic issues.

(c) *Duties and responsibilities.* (1) A policy council is responsible for activities specified at section 642(c)(2)(D) of the Act. A policy committee must approve and submit to the delegate agency its decisions in each of the following areas referenced at section 642(c)(2)(D)(i) through (vii) of the Act.

(2) A policy council, and a policy committee at the delegate level, must use ongoing monitoring results, data on school readiness goals, other information described in § 1302.102, and information described in section 642(d)(2) of the Act to conduct its responsibilities.

(d) *Term.* (1) A member will serve for one year.

(2) If the member intends to serve for another year, s/he must stand for re-election.

(3) The policy council, and policy committee at the delegate level, must include in its bylaws how many one-year terms, not to exceed five terms, a person may serve.

(4) A program must seat a successor policy council, or policy committee at the delegate level, before an existing policy council, or policy committee at the delegate level, may be dissolved.

(e) *Reimbursement.* A program must enable low-income members to participate fully in their policy council or policy committee responsibilities by providing, if necessary, reimbursements for reasonable expenses incurred by the low-income members.

§ 1301.4 Parent committees.

(a) *Establishing parent committees.* A program must establish a parent committee comprised exclusively of parents of currently enrolled children as early in the program year as possible. This committee must be established at the center level for center-based programs and at the local program level for other program options. When a program operates more than one option, parents may choose to have a separate committee for each option or combine membership. A program must ensure that parents of currently enrolled children understand the process for elections to the policy council or policy committee and other leadership opportunities.

(b) *Requirements of parent committees.* Within the parent committee structure, a program may determine the best methods to engage families using strategies that are most effective in their community, as long as the program ensures the parent committee carries out the following minimum responsibilities:

(1) Advise staff in developing and implementing local program policies, activities, and services to ensure they meet the needs of children and families;

(2) Have a process for communication with the policy council and policy committee; and

(3) Within the guidelines established by the governing body, policy council or policy committee, participate in the recruitment and screening of Early Head Start and Head Start employees.

§ 1301.5 Training.

An agency must provide appropriate training and technical assistance or orientation to the governing body, any advisory committee members, and the policy council, including training on program performance standards and training indicated in § 1302.12(m) to ensure the members understand the information they receive and can effectively oversee and participate in the programs in the Head Start agency.

§ 1301.6 Impasse procedures.

(a) To facilitate meaningful consultation and collaboration about decisions of the governing body and the policy council, each agency's governing body and policy council jointly must establish written procedures for resolving internal disputes between the governing board and policy council in a timely manner that include impasse procedures. These procedures must:

(1) Demonstrate that the governing body considers proposed decisions from the policy council and that the policy council considers proposed decisions from the governing body;

(2) If there is a disagreement, require the governing body and the policy council to notify the other in writing why it does not accept a decision; and,

(3) Describe a decision-making process and a timeline to resolve disputes and reach decisions that are not arbitrary, capricious, or illegal.

(b) If the agency's decision-making process does not result in a resolution and an impasse continues, the governing body and policy council must select a mutually agreeable third party mediator and participate in a formal process of mediation that leads to a resolution of the dispute.

(c) For all programs except American Indian and Alaska Native programs, if no resolution is reached with a mediator, the governing body and policy council must select a mutually agreeable arbitrator whose decision is final.

PART 1302—PROGRAM OPERATIONS

Sec.
1302.1 Overview.

Subpart A—Eligibility, Recruitment, Selection, Enrollment, and Attendance

1302.10 Purpose.
1302.11 Determining community strengths, needs, and resources.
1302.12 Determining, verifying, and documenting eligibility.
1302.13 Recruitment of children.
1302.14 Selection process.
1302.15 Enrollment.
1302.16 Attendance.
1302.17 Suspension and expulsion.
1302.18 Fees.

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1302.20 Determining program structure.
1302.21 Center-based option.
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1302.23 Family child care option.
1302.24 Locally-designed program option variations.

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Subpart D—Health Program Services

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1302.60 Full participation in program services and activities.
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1302.63 Coordination and collaboration with the local agency responsible for implementing IDEA.

Subpart G—Transition Services

1302.70 Transitions from Early Head Start.
1302.71 Transitions from Head Start to kindergarten.
1302.72 Transitions between programs.

Subpart H—Services to Enrolled Pregnant Women

1302.80 Enrolled pregnant women.
1302.81 Prenatal and postpartum information, education, and services.
1302.82 Family partnership services for enrolled pregnant women.

Subpart I—Human Resources Management

1302.90 Personnel policies.
1302.91 Staff qualification and competency requirements.
1302.92 Training and professional development.
1302.93 Staff health and wellness.
1302.94 Volunteers.

Subpart J—Program Management and Quality Improvement

1302.100 Purpose.
1302.101 Management system.
1302.102 Achieving program goals.
1302.103 Implementation of program performance standards.

Authority: 42 U.S.C. 9801 *et seq.*

§ 1302.1 Overview.

This part implements these statutory requirements in Sections 641A, 645, 645A, and 648A of the Act by describing all of the program performance standards that are required to operate Head Start, Early Head Start, American Indian and Alaska Native and Migrant or Seasonal Head Start programs. The part covers the full range of operations from enrolling eligible children and providing program services to those children and their families, to managing programs to ensure staff are qualified and supported to effectively provide services. This part also focuses on using data through ongoing program improvement to ensure high-quality service. As required in the Act, these provisions do not narrow the scope or quality of services covered in previous regulations. Instead, these regulations raise the quality standard to reflect science and best practices, and streamline and simplify requirements so programs can better understand what is required for quality services.

Subpart A—Eligibility, Recruitment, Selection, Enrollment, and Attendance

§ 1302.10 Purpose.

This subpart describes requirements of grantees for determining community strengths, needs and resources as well as recruitment areas. It contains requirements and procedures for the eligibility determination, recruitment, selection, enrollment and attendance of children and explains the policy concerning the charging of fees.

§ 1302.11 Determining community strengths, needs, and resources.

(a) *Service area.* (1) A program must propose a service area in the grant application and define the area by county or sub-county area, such as a municipality, town or census tract or jurisdiction of a federally recognized Indian reservation.

(i) A tribal program may propose a service area that includes areas where members of Indian tribes or those eligible for such membership reside, including but not limited to Indian reservation land, areas designated as near-reservation by the Bureau of Indian Affairs (BIA) provided that the service area is approved by the tribe's governing council, Alaska Native Villages, Alaska Native Regional Corporations with land-based authorities, Oklahoma Tribal Statistical Areas, and Tribal Designated Statistical Areas where federally recognized Indian tribes do not have a federally established reservation.

(ii) If the tribe's service area includes any area specified in paragraph (a)(1)(i) of this section, and that area is also served by another program, the tribe may serve children from families who are members of or eligible to be members of such tribe and who reside in such areas as well as children from families who are not members of the tribe, but who reside within the tribe's established service area.

(2) If a program decides to change the service area after ACF has approved its grant application, the program must submit to ACF a new service area proposal for approval.

(b) *Community wide strategic planning and needs assessment (community assessment).* (1) To design a program that meets community needs, and builds on strengths and resources, a program must conduct a community assessment at least once over the five-year grant period. The community assessment must use data that describes community strengths, needs, and resources and include, at a minimum:

(i) The number of eligible infants, toddlers, preschool age children, and expectant mothers, including their geographic location, race, ethnicity, and languages they speak, including:

(A) Children experiencing homelessness in collaboration with, to the extent possible, McKinney-Vento Local Education Agency Liaisons (42 U.S.C. 11432 (6)(A));

(B) Children in foster care; and

(C) Children with disabilities, including types of disabilities and relevant services and resources provided to these children by community agencies;

(ii) The education, health, nutrition and social service needs of eligible children and their families, including prevalent social or economic factors that impact their well-being;

(iii) Typical work, school, and training schedules of parents with eligible children;

(iv) Other child development, child care centers, and family child care programs that serve eligible children, including home visiting, publicly funded state and local preschools, and the approximate number of eligible children served;

(v) Resources that are available in the community to address the needs of eligible children and their families; and,

(vi) Strengths of the community.

(2) A program must annually review and update the community assessment to reflect any significant changes including increased availability of publicly-funded pre-kindergarten-(including an assessment of how the pre-kindergarten available in the community meets the needs of the parents and children served by the program, and whether it is offered for a full school day), rates of family and child homelessness, and significant shifts in community demographics and resources.

(3) A program must consider whether the characteristics of the community allow it to include children from diverse economic backgrounds that would be supported by other funding sources, including private pay, in addition to the program's eligible funded enrollment. A program must not enroll children from diverse economic backgrounds if it would result in a program serving less than its eligible funded enrollment.

§ 1302.12 Determining, verifying, and documenting eligibility.

(a) *Process overview.* (1) Program staff must:

(i) Conduct an in-person interview with each family, unless paragraph (a)(2) of this section applies;

(ii) Verify information as required in paragraphs (h) and (i) of this section; and,

(iii) Create an eligibility determination record for enrolled participants according to paragraph (k) of this section.

(2) Program staff may interview the family over the telephone if an in-person interview is not possible or convenient for the family.

(3) If a program has an alternate method to reasonably determine eligibility based on its community assessment, geographic and administrative data, or from other reliable data sources, it may petition the responsible HHS official to waive requirements in paragraphs (a)(1)(i) and (ii) of this section.

(b) *Age requirements.* (1) For Early Head Start, except when the child is transitioning to Head Start, a child must be an infant or a toddler younger than three years old.

(2) For Head Start, a child must:

(i) Be at least three years old or, turn three years old by the date used to determine eligibility for public school in the community in which the Head Start program is located; and,

(ii) Be no older than the age required to attend school.

(3) For Migrant or Seasonal Head Start, a child must be younger than compulsory school age by the date used to determine public school eligibility for the community in which the program is located.

(c) *Eligibility requirements.* (1) A pregnant woman or a child is eligible if:

(i) The family's income is equal to or below the poverty line; or,

(ii) The family is eligible for or, in the absence of child care, would be potentially eligible for public assistance; including TANF child-only payments; or,

(iii) The child is homeless, as defined in part 1305; or,

(iv) The child is in foster care.

(2) If the family does not meet a criterion under paragraph (c)(1) of this section, a program may enroll a child who would benefit from services, provided that these participants only make up to 10 percent of a program's enrollment in accordance with paragraph (d) of this section.

(d) *Additional allowances for programs.* (1) A program may enroll an additional 35 percent of participants whose families do not meet a criterion described in paragraph (c) of this section and whose incomes are below 130 percent of the poverty line, if the program:

(i) Establishes and implements outreach, and enrollment policies and procedures to ensure it is meeting the needs of eligible pregnant women, children, and children with disabilities, before serving pregnant women or children who do not meet the criteria in paragraph (c) of this section; and,

(ii) Establishes criteria that ensure pregnant women and children eligible under the criteria listed in paragraph (c) of this section are served first.

(2) If a program chooses to enroll participants who do not meet a criterion in paragraph (c) of this section, and whose family incomes are between 100 and 130 percent of the poverty line, it must be able to report to the Head Start regional program office:

(i) How it is meeting the needs of low-income families or families potentially eligible for public assistance, homeless children, and children in foster care, and include local demographic data on these populations;

(ii) Outreach and enrollment policies and procedures that ensure it is meeting the needs of eligible children or pregnant women, before serving over-income children or pregnant women;

(iii) Efforts, including outreach, to be fully enrolled with eligible pregnant women or children;

(iv) Policies, procedures, and selection criteria it uses to serve eligible children;

(v) Its current enrollment and its enrollment for the previous year;

(vi) The number of pregnant women and children served, disaggregated by the eligibility criteria in paragraphs (c) and (d)(1) of this section; and,

(vii) The eligibility criteria category of each child on the program's waiting list.

(e) *Additional allowances for Indian tribes.* (1) Notwithstanding paragraph (c)(2) of this section, a tribal program may fill more than 10 percent of its enrollment with participants who are not eligible under the criteria in paragraph (c) of this section, if:

(i) The tribal program has served all eligible pregnant women or children who wish to be enrolled from Indian and non-Indian families living within the approved service area of the tribal agency;

(ii) The tribe has resources within its grant, without using additional funds from HHS intended to expand Early Head Start or Head Start services, to enroll pregnant women or children whose family incomes exceed low-income guidelines or who are not otherwise eligible; and,

(iii) At least 51 percent of the program's participants meet an eligibility criterion under paragraph (c)(1) of this section.

(2) If another program does not serve the approved service area, the program must serve all eligible Indian and non-Indian pregnant women or children who wish to enroll before serving over-income pregnant women or children.

(3) A program that meets the conditions of this paragraph (e) must annually set criteria that are approved by the policy council and the tribal council for selecting over-income pregnant women or children who would benefit from program services.

(4) An Indian tribe or tribes that operates both an Early Head Start program and a Head Start program may, at its discretion, at any time during the grant period involved, reallocate funds between the Early Head Start program and the Head Start program in order to address fluctuations in client populations, including pregnant women and children from birth to compulsory school age. The reallocation of such funds between programs by an Indian tribe or tribes during a year may not serve as a basis for any reduction of the base grant for either program in succeeding years.

(f) *Migrant or Seasonal eligibility requirements.* A child is eligible for Migrant or Seasonal Head Start, if the family meets an eligibility criterion in paragraphs (c) and (d) of this section; and the family's income comes primarily from agricultural work.

(g) *Eligibility requirements for communities with 1,000 or fewer individuals.* (1) A program may establish its own criteria for eligibility provided that it meets the criteria outlined in section 645(a)(2) of the Act.

(2) No child residing in such community whose family is eligible under criteria described in paragraphs (c) through (f) of this section, may be denied an opportunity to participate in the program under the eligibility criteria established under this paragraph (g).

(h) *Verifying age.* Program staff must verify a child's age according to program policies and procedures. A program's policies and procedures cannot require families to provide documents that confirm a child's age, if doing so creates a barrier for the family to enroll the child.

(i) *Verifying eligibility.* (1) To verify eligibility based on income, program staff must use tax forms, pay stubs, or other proof of income to determine the family income for the relevant time period.

(i) If the family cannot provide tax forms, pay stubs, or other proof of income for the relevant time period, program staff may accept written statements from employers, including individuals who are self-employed, for the relevant time period and use information provided to calculate total annual income with appropriate multipliers.

(ii) If the family reports no income for the relevant time period, a program may accept the family's signed declaration to that effect, if program staff describes efforts made to verify the family's income, and explains how the family's total income was calculated or seeks information from third parties about the family's eligibility, if the family gives written consent. If a family gives consent to contact third parties, program staff must adhere to program safety and privacy policies and procedures and ensure the eligibility determination record adheres to paragraph (k)(2) of this section.

(iii) If the family can demonstrate a significant change in income for the relevant time period, program staff may consider current income circumstances.

(2) To verify whether a family is eligible for, or in the absence of child care, would be potentially eligible for public assistance, the program must have documentation from either the state, local, or tribal public assistance agency that shows the family either receives public assistance or that shows the family is potentially eligible to receive public assistance.

(3) To verify whether a family is homeless, a program may accept a written statement from a homeless services provider, school personnel, or other service agency attesting that the child is homeless or any other documentation that indicates homelessness, including documentation from a public or private agency, a declaration, information gathered on enrollment or application forms, or notes from an interview with staff to establish the child is homeless; or any other document that establishes homelessness.

(i) If a family can provide one of the documents described in this paragraph (i)(3), program staff must describe efforts made to verify the accuracy of the information provided and state whether the family is eligible because they are homeless.

(ii) If a family cannot provide one of the documents described in this paragraph (i)(3) to prove the child is homeless, a program may accept the family's signed declaration to that effect, if, in a written statement, program staff describe the child's living situation that meets the definition of homeless in part 1305 of this chapter.

(iii) Program staff may seek information from third parties who have firsthand knowledge about a family's living situation, if the family gives written consent. If the family gives consent to contact third parties, program staff must adhere to program privacy policies and procedures and ensure the eligibility determination record adheres to paragraph (k) of this section.

(4) To verify whether a child is in foster care, program staff must accept either a court order or other legal or government-issued document, a written statement from a government child welfare official that demonstrates the child is in foster care, or proof of a foster care payment.

(j) *Eligibility duration.* (1) If a child is determined eligible under this section and is participating in a Head Start program, he or she will remain eligible through the end of the succeeding program year except that the Head Start program may choose not to enroll a child when there are compelling reasons for the child not to remain in Head Start, such as when there is a change in the child's family income and there is a child with a greater need for Head Start services.

(2) Children who are enrolled in a program receiving funds under the authority of section 645A of the Act remain eligible while they participate in the program.

(3) If a child moves from an Early Head Start program to a Head Start program, program staff must verify the family's eligibility again.

(4) If a program operates both an Early Head Start and a Head Start program, and the parents wish to enroll their child who has been enrolled in the program's Early Head Start, the program must ensure, whenever possible, the child receives Head Start services until enrolled in school, provided the child is eligible.

(k) *Records.* (1) A program must keep eligibility determination records for each participant and ongoing records of the eligibility training for staff required by paragraph (m) of this section. A program may keep these records electronically.

(2) Each eligibility determination record must include:

(i) Copies of any documents or statements, including declarations, that are deemed necessary to verify eligibility under paragraphs (h) and (i) of this section;

(ii) A statement that program staff has made reasonable efforts to verify information by:

(A) Conducting either an in-person, or a telephone interview with the family as described under paragraph (a)(1)(i) or (a)(2) of this section; and,

(B) Describing efforts made to verify eligibility, as required under paragraphs (h) through (i) of this section; and, collecting documents required for third party verification that includes the family's written consent to contact each third party, the third parties' names, titles, and affiliations, and information from third parties regarding the family's eligibility.

(iii) A statement that identifies whether:

(A) The family's income is below income guidelines for its size, and lists the family's size;

(B) The family is eligible for or, in the absence of child care, potentially eligible for public assistance;

(C) The child is a homeless child or the child is in foster care;

(D) The family was determined to be eligible under the criterion in paragraph (c)(2) of this section; or,

(E) The family was determined to be eligible under the criterion in paragraph (d)(1) of this section.

(3) A program must keep eligibility determination records for those currently enrolled, as long as they are enrolled, and, for one year after they have either stopped receiving services; or are no longer enrolled.

(l) *Program policies and procedures on violating eligibility determination regulations.* A program must establish written policies and procedures that describe all actions taken against staff who intentionally violate federal and program eligibility determination regulations and who enroll pregnant women and children that are not eligible to receive Early Head Start or Head Start services.

(m) *Training on eligibility.* (1) A program must train all governing body, policy council, management, and staff who determine eligibility on applicable federal regulations and program policies and procedures. Training must, at a minimum:

(i) Include methods on how to collect complete and accurate eligibility information from families and third party sources;

(ii) Incorporate strategies for treating families with dignity and respect and for dealing with possible issues of domestic violence, stigma, and privacy; and,

(iii) Explain program policies and procedures that describe actions taken against staff, families, or participants who attempt to provide or intentionally provide false information.

(2) A program must train management and staff members who make eligibility determinations within 90 days of hiring new staff.

(3) A program must train all governing body and policy council members within 180 days of the beginning of the term of a new governing body or policy council.

(4) A program must develop policies on how often training will be provided after the initial training.

§ 1302.13 Recruitment of children.

In order to reach those most in need of services, a program must develop and implement a recruitment process designed to actively inform all families with eligible children within the recruitment area of the availability of program services, and encourage and assist them in applying for admission to the program. A program must include specific efforts to actively locate and recruit children with disabilities and other vulnerable children, including homeless children and children in foster care.

§ 1302.14 Selection process.

(a) *Selection criteria.* (1) A program must annually establish selection criteria that weigh the prioritization of selection of participants, based on community needs identified in the community needs assessment as described in § 1302.11(b), and including family income, whether the child is homeless, whether the child is in foster care, the child's age, whether the child is eligible for special education and related services, or early intervention services, as appropriate, as determined under the Individuals with Disabilities Education Act (IDEA) (20 U.S.C. 1400 *et seq.*) and, other relevant family or child risk factors.

(2) If a program serves migrant or seasonal families, it must select participants according to criteria in paragraph (a)(1) of this section, and give priority to children whose families can demonstrate they have relocated frequently within the past two-years to pursue agricultural work.

(3) If a program operates in a service area where Head Start eligible children can enroll in high-quality publicly funded pre-kindergarten for a full school day, the program must prioritize younger children as part of the selection criteria in paragraph (a)(1) of this section. If this priority would disrupt partnerships with local education agencies, then it is not required. An American Indian and Alaska Native or Migrant or Seasonal Head Start program must consider whether such prioritization is appropriate in their community.

(4) A program must not deny enrollment based on a disability or chronic health condition or its severity.

(b) *Children eligible for services under IDEA.* (1) A program must ensure at least 10 percent of its total funded enrollment is filled by children eligible for services under IDEA, unless the responsible HHS official grants a waiver.

(2) If the requirement in paragraph (b)(1) of this section has been met, children eligible for services under IDEA should be prioritized for the available slots in accordance with the program's selection criteria described in paragraph (a) of this section.

(c) *Waiting lists.* A program must develop at the beginning of each enrollment year and maintain during the year a waiting list that ranks children according to the program's selection criteria.

§ 1302.15 Enrollment.

(a) *Funded enrollment.* A program must maintain its funded enrollment level and fill any vacancy as soon as possible. A program must fill any vacancy within 30 days.

(b) *Continuity of enrollment.* (1) A program must make efforts to maintain enrollment of eligible children for the following year.

(2) Under exceptional circumstances, a program may maintain a child's enrollment in Head Start for a third year, provided that family income is verified again. A program may maintain a child's enrollment in Early Head Start as described in § 1302.12(j)(2).

(3) If a program serves homeless children or children in foster care, it must make efforts to maintain the child's enrollment regardless of whether the family or child moves to a different service area, or transition the child to a program in a different service area, as required in § 1302.72(a), according to the family's needs.

(c) *Reserved slots.* If a program determines from the community assessment there are families experiencing homelessness in the area, or children in foster care that could benefit from services, the program may reserve one or more enrollment slots for pregnant women and children experiencing homelessness and children in foster care, when a vacancy occurs. No more than three percent of a program's funded enrollment slots may be reserved. If the reserved enrollment slot is not filled within 30 days, the enrollment slot becomes vacant and then must be filled in accordance with paragraph (a) of this section.

(d) *Other enrollment.* Children from diverse economic backgrounds who are funded with other sources, including private pay, are not considered part of a program's eligible funded enrollment.

(e) *State immunization enrollment requirements.* A program must comply with state immunization enrollment and attendance requirements, with the exception of homeless children as described in § 1302.16(c)(1).

(f) *Voluntary parent participation.* Parent participation in any program activity is voluntary, including consent for data sharing, and is not required as a condition of the child's enrollment.

§ 1302.16 Attendance.

(a) *Promoting regular attendance.* A program must track attendance for each child.

(1) A program must implement a process to ensure children are safe when they do not arrive at school. If a child is unexpectedly absent and a parent has not contacted the program within one hour of program start time, the program must attempt to contact the parent to ensure the child's well-being.

(2) A program must implement strategies to promote attendance. At a minimum, a program must:

(i) Provide information about the benefits of regular attendance;

(ii) Support families to promote the child's regular attendance;

(iii) Conduct a home visit or make other direct contact with a child's parents if a child has multiple unexplained absences (such as two consecutive unexplained absences); and,

(iv) Within the first 60 days of program operation, and on an ongoing basis thereafter, use individual child attendance data to identify children with patterns of absence that put them at risk of missing ten percent of program days per year and develop appropriate strategies to improve individual attendance among identified children, such as direct contact with parents or intensive case management, as necessary.

(3) If a child ceases to attend, the program must make appropriate efforts to reengage the family to resume attendance, including as described in paragraph (a)(2) of this section. If the child's attendance does not resume, then the program must consider that slot vacant. This action is not considered expulsion as described in § 1302.17.

(b) *Managing systematic program attendance issues.* If a program's monthly average daily attendance rate falls below 85 percent, the program must analyze the causes of absenteeism to identify any systematic issues that contribute to the program's absentee rate. The program must use this data to make necessary changes in a timely manner as part of ongoing oversight and correction as described in § 1302.102(b) and inform its continuous improvement efforts as described in § 1302.102(c).

(c) *Supporting attendance of homeless children.* (1) If a program determines a child is eligible under § 1302.12(c)(1)(iii), it must allow the child to attend for up to 90 days or as long as allowed under state licensing requirements, without immunization and other records, to give the family reasonable time to present these documents. A program must work with families to get children immunized as soon as possible in order to comply with state licensing requirements.

(2) If a child experiencing homelessness is unable to attend classes regularly because the family does not have transportation to and from the program facility, the program must utilize community resources, where possible, to provide transportation for the child.

§ 1302.17 Suspension and expulsion.

(a) *Limitations on suspension.* (1) A program must prohibit or severely limit the use of suspension due to a child's behavior. Such suspensions may only be temporary in nature.

(2) A temporary suspension must be used only as a last resort in extraordinary circumstances where there is a serious safety threat that cannot be reduced or eliminated by the provision of reasonable modifications.

(3) Before a program determines whether a temporary suspension is necessary, a program must engage with a mental health consultant, collaborate with the parents, and utilize appropriate community resources—such as behavior coaches, psychologists, other appropriate specialists, or other resources—as needed, to determine no other reasonable option is appropriate.

(4) If a temporary suspension is deemed necessary, a program must help the child return to full participation in all program activities as quickly as possible while ensuring child safety by:

(i) Continuing to engage with the parents and a mental health consultant, and continuing to utilize appropriate community resources;

(ii) Developing a written plan to document the action and supports needed;

(iii) Providing services that include home visits; and,

(iv) Determining whether a referral to a local agency responsible for implementing IDEA is appropriate.

(b) *Prohibition on expulsion.* (1) A program cannot expel or unenroll a child from Head Start because of a child's behavior.

(2) When a child exhibits persistent and serious challenging behaviors, a program must explore all possible steps and document all steps taken to address such problems, and facilitate the child's safe participation in the program. Such steps must include, at a minimum, engaging a mental health consultant, considering the appropriateness of providing appropriate services and supports under section 504 of the Rehabilitation Act to ensure that the child who satisfies the definition of disability in 29 U.S.C. 705(9)(b) of the Rehabilitation Act is not excluded from the program on the basis of disability, and consulting with the parents and the child's teacher, and:

(i) If the child has an individualized family service plan (IFSP) or individualized education program (IEP), the program must consult with the agency responsible for the IFSP or IEP to ensure the child receives the needed support services; or,

(ii) If the child does not have an IFSP or IEP, the program must collaborate, with parental consent, with the local agency responsible for implementing IDEA to determine the child's eligibility for services.

(3) If, after a program has explored all possible steps and documented all steps taken as described in paragraph (b)(2) of this section, a program, in consultation with the parents, the child's teacher, the agency responsible for implementing IDEA (if applicable), and the mental health consultant, determines that the child's continued enrollment presents a continued serious safety threat to the child or other enrolled children and determines the program is not the most appropriate placement for the child, the program must work with such entities to directly facilitate the transition of the child to a more appropriate placement.

§ 1302.18 Fees.

(a) *Policy on fees.* A program must not charge eligible families a fee to participate in Head Start, including special events such as field trips, and cannot in any way condition an eligible child's enrollment or participation in the program upon the payment of a fee.

(b) *Allowable fees.* (1) A program must only accept a fee from families of enrolled children for services that are in addition to services funded by Head Start, such as child care before or after funded Head Start hours. A program may not condition a Head Start child's enrollment on the ability to pay a fee for additional hours.

(2) In order to support programs serving children from diverse economic backgrounds or using multiple funding sources, a program may charge fees to private pay families and other non-Head Start enrolled families to the extent allowed by any other applicable federal, state or local funding sources.

Subpart B—Program Structure

§ 1302.20 Determining program structure.

(a) *Choose a program option.* (1) A program must choose to operate one or more of the following program options: Center-based, home-based, family child care, or an approved locally-designed variation as described in § 1302.24. The program option(s) chosen must meet the needs of children and families based on the community assessment described in § 1302.11(b). A Head Start program serving preschool-aged children may not provide only the option described in § 1302.22(a) and (c)(2).

(2) To choose a program option and develop a program calendar, a program must consider in conjunction with the annual review of the community assessment described in § 1302.11(b)(2), whether it would better meet child and family needs through conversion of existing slots to full school day or full working day slots, extending the program year, conversion of existing Head Start slots to Early Head Start slots as described in paragraph (c) of this section, and ways to promote continuity of care and services. A program must work to identify alternate sources to support full working day services. If no additional funding is available, program resources may be used.

(b) *Comprehensive services.* All program options must deliver the full range of services, as described in subparts C, D, E, F, and G of this part, except that §§ 1302.30 through 1302.32 and § 1302.34 do not apply to home-based options.

(c) *Conversion.* (1) Consistent with section 645(a)(5) of the Head Start Act, grantees may request to convert Head Start slots to Early Head Start slots through the re-funding application process or as a separate grant amendment.

(2) Any grantee proposing a conversion of Head Start services to Early Head Start services must obtain policy council and governing body approval and submit the request to their regional office.

(3) With the exception of American Indian and Alaska Native grantees as described in paragraph (c)(4) of this section, the request to the regional office must include:

(i) A grant application budget and a budget narrative that clearly identifies the funding amount for the Head Start and Early Head Start programs before and after the proposed conversion;

(ii) The results of the community assessment demonstrating how the proposed use of funds would best meet the needs of the community, including a description of how the needs of eligible Head Start children will be met in the community when the conversion takes places;

(iii) A revised program schedule that describes the program option(s) and the number of funded enrollment slots for Head Start and Early Head Start programs before and after the proposed conversion;

(iv) A description of how the needs of pregnant women, infants, and toddlers will be addressed;

(v) A discussion of the agency's capacity to carry out an effective Early Head Start program in accordance with the requirements of section 645A(b) of the Head Start Act and all applicable regulations;

(vi) Assurances that the agency will participate in training and technical assistance activities required of all Early Head Start grantees;

(vii) A discussion of the qualifications and competencies of the child development staff proposed for the Early Head Start program, as well as a description of the facilities and program infrastructure that will be used to support the new or expanded Early Head Start program;

(viii) A discussion of any one-time funding necessary to implement the proposed conversion and how the agency intends to secure such funding; and,

(ix) The proposed timetable for implementing this conversion, including updating school readiness goals as described in subpart J of this part.

(4) Consistent with section 645(d)(3) of the Act, any American Indian and Alaska Native grantee that operates both an Early Head Start program and a Head Start program may reallocate funds between the programs at its discretion and at any time during the grant period involved, in order to address fluctuations in client populations. An American Indian and Alaska Native program that exercises this discretion must notify the regional office.

(d) *Source of funding.* A program may consider hours of service that meet the Head Start Program Performance Standards, regardless of the source of funding, as hours of planned class operations for the purposes of meeting the Head Start and Early Head Start service duration requirements in this subpart.

§ 1302.21 Center-based option.

(a) *Setting.* The center-based option delivers the full range of services, consistent with § 1302.20(b). Education and child development services are delivered primarily in classroom settings.

(b) *Ratios and group size.* (1) Staff-child ratios and group size maximums must be determined by the age of the majority of children and the needs of children present. A program must determine the age of the majority of children in a class at the start of the year and may adjust this determination during the program year, if necessary. Where state or local licensing requirements are more stringent than the teacher-child ratios and group size specifications in this section, a program must meet the stricter requirements. A program must maintain appropriate ratios during all hours of program operation, except:

(i) For brief absences of a teaching staff member for no more than five minutes; and,

(ii) During nap time, one teaching staff member may be replaced by one staff member or trained volunteer who does not meet the teaching qualifications required for the age.

(2) An Early Head Start or Migrant or Seasonal Head Start class that serves children under 36 months old must have two teachers with no more than eight children, or three teachers with no more than nine children. Each teacher must be assigned consistent, primary responsibility for no more than four children to promote continuity of care for individual children. A program must minimize teacher changes throughout a child's enrollment, whenever possible, and consider mixed age group classes to support continuity of care.

(3) A class that serves a majority of children who are three years old must have no more than 17 children with a teacher and teaching assistant or two teachers. A double session class that serves a majority of children who are three years old must have no more than 15 children with a teacher and teaching assistant or two teachers.

(4) A class that serves a majority of children who are four and five years old must have no more than 20 children with a teacher and a teaching assistant or two teachers. A double session class that serves a majority of children who are four and five years old must have no more than 17 children with a teacher and a teaching assistant or two teachers.

TABLE TO § 1302.21(b)—CENTER-BASED GROUP SIZE

4 and 5 year olds	No more than 20 children enrolled in any class. No more than 17 children enrolled in any double session class.
3 year olds	No more than 17 children enrolled in any class. No more than 15 children enrolled in any double session class.
Under 3 years old	No more than 8 or 9 children enrolled in any class, depending on the number of teachers.

(c) *Service duration*—(1) *Early Head Start.* (i) By August 1, 2018, a program must provide 1,380 annual hours of planned class operations for all enrolled children.

(ii) A program that is designed to meet the needs of young parents enrolled in school settings may meet the service duration requirements in paragraph (c)(1)(i) of this section if it operates a center-based program schedule during the school year aligned with its local education agency requirements and provides regular home-based services during the summer break.

(2) *Head Start.* (i) Until a program is operating all of its Head Start center-based funded enrollment at the standard described in paragraph (c)(2)(iv) or (v) of this section, a program must provide, at a minimum, at least 160 days per year of planned class operations if it operates for five days per week, or at least 128 days per year if it operates four days per week. Classes must operate for a minimum of 3.5 hours per day.

(ii) Until a program is operating all of its Head Start center-based funded enrollment at the standard described in paragraph (c)(2)(iv) or (v) of this section, if a program operates a double session variation, it must provide classes for four days per week for a minimum of 128 days per year and 3.5 hours per day. Each double session class staff member must be provided adequate break time during the course of the day. In addition, teachers, aides, and volunteers must have appropriate time to prepare for each session together, to set up the classroom environment, and to give individual attention to children entering and leaving the center.

(iii) By August 1, 2019, a program must provide 1,020 annual hours of planned class operations over the course of at least eight months per year for at least 50 percent of its Head Start center-based funded enrollment.

(iv) By August 1, 2021, a program must provide 1,020 annual hours of planned class operations over the course of at least eight months per year for all of its Head Start center-based funded enrollment.

(v) A Head Start program providing fewer than 1,020 annual hours of planned class operations or fewer than eight months of service is considered to meet the requirements described in paragraphs (c)(2)(iii) and (iv) of this section if its program schedule aligns with the annual hours required by its local education agency for grade one and such alignment is necessary to support partnerships for service delivery.

(3) *Secretarial determination.* (i) On or before February 1, 2018, the Secretary may lower the required percentage described in paragraph (c)(2)(iii) of this section, based on an assessment of the availability of sufficient funding to mitigate a substantial reduction in funded enrollment; and,

(ii) On or before February 1, 2020, the Secretary may lower the required percentage described in paragraph (c)(2)(iv) of this section, based on an assessment of the availability of sufficient funding to mitigate a substantial reduction in funded enrollment.

(4) *Extension.* If an extension is necessary to ensure children enrolled in the program on November 7, 2016 are not displaced from the Early Head Start or Head Start program, a program may request a one-year extension from the responsible HHS official of the requirements outlined in paragraphs (c)(1) and (c)(2)(iii) of this section.

(5) *Exemption for Migrant or Seasonal Head Start programs.* A Migrant or Seasonal program is not subject to the requirements described in § 1302.21(c)(1) or (2), but must make every effort to provide as many days and hours of service as possible to each child and family.

(6) *Calendar planning.* A program must:

(i) Plan its year using a reasonable estimate of the number of days during a year that classes may be closed due to problems such as inclement weather; and,

(ii) Make every effort to schedule makeup days using existing resources if hours of planned class operations fall below the number required per year.

(d) *Licensing and square footage requirements.* (1) The facilities used by a program must meet state, tribal, or local licensing requirements, even if exempted by the licensing entity. When state, tribal, or local requirements vary from Head Start requirements, the most stringent provision takes precedence.

(2) A center-based program must have at least 35 square feet of usable indoor space per child available for the care and use of children (exclusive of bathrooms, halls, kitchen, staff rooms, and storage places) and at least 75 square feet of usable outdoor play space per child.

(3) A program that operates two or more groups within an area must ensure clearly defined, safe divisions to separate groups. A program must ensure such spaces are learning environments that facilitate the implementation of the requirements in subpart C of this part. The divisions must limit noise transfer from one group to another to prevent disruption of an effective learning environment.

§ 1302.22 Home-based option.

(a) *Setting.* The home-based option delivers the full range of services, consistent with § 1302.20(b), through visits with the child's parents, primarily in the child's home and through group socialization opportunities in a Head Start classroom, community facility, home, or on field trips. For Early Head Start programs, the home-based option may be used to deliver services to some or all of a program's enrolled children. For Head Start programs, the home-based option may only be used to deliver services to a portion of a program's enrolled children.

(b) *Caseload.* A program that implements a home-based option must maintain an average caseload of 10 to 12 families per home visitor with a maximum of 12 families for any individual home visitor.

(c) *Service duration*—(1) *Early Head Start.* By August 1, 2017, an Early Head Start home-based program must:

(i) Provide one home visit per week per family that lasts at least an hour and a half and provide a minimum of 46 visits per year; and,

(ii) Provide, at a minimum, 22 group socialization activities distributed over the course of the program year.

(2) *Head Start.* A Head Start home-based program must:

(i) Provide one home visit per week per family that lasts at least an hour and a half and provide a minimum of 32 visits per year; and,

(ii) Provide, at a minimum, 16 group socialization activities distributed over the course of the program year.

(3) *Meeting minimum requirements.* A program that implements a home-based option must:

(i) Make up planned home visits or scheduled group socialization activities that were canceled by the program, and to the extent possible attempt to make up planned home visits canceled by the family, when this is necessary to meet the minimums described in paragraphs (c)(1) and (2) of this section; and,

(ii) Not replace home visits or scheduled group socialization activities for medical or social service appointments for the purposes of meeting the minimum requirements described in paragraphs (c)(1) and (2) of this section.

(d) *Safety requirements.* The areas for learning, playing, sleeping, toileting, preparing food, and eating in facilities used for group socializations in the home-based option must meet the safety standards described in § 1302.47(1)(ii) through (viii).

§ 1302.23 Family child care option.

(a) *Setting.* The family child care program option delivers the full range of services, consistent with § 1302.20(b). Education and child development services are primarily delivered by a family child care provider in their home or other family-like setting. A program may choose to offer the family child care option if:

(1) The program has a legally binding agreement with one or more family child care provider(s) that clearly defines the roles, rights, and responsibilities of each party, or the program is the employer of the family child care provider, and ensures children and families enrolled in this option receive the full range of services described in subparts C, D, E, F, and G of this part; and,

(2) The program ensures family child care homes are available that can accommodate children and families with disabilities.

(b) *Ratios and group size.* (1) A program that operates the family child care option where Head Start children are enrolled must ensure group size does not exceed the limits specified in this section. If the family child care provider's own children under the age of six are present, they must be included in the group size.

(2) When there is one family child care provider, the maximum group size is six children and no more than two of the six may be under 24 months of age. When there is a provider and an assistant, the maximum group size is twelve children with no more than four of the twelve children under 24 months of age.

(3) One family child care provider may care for up to four children younger than 36 months of age with a maximum group size of four children, and no more than two of the four children may be under 18 months of age.

(4) A program must maintain appropriate ratios during all hours of program operation. A program must ensure providers have systems to ensure the safety of any child not within view for any period. A program must make substitute staff and assistant providers available with the necessary training and experience to ensure quality services to children are not interrupted.

(c) *Service duration.* Whether family child care option services are provided directly or via contractual arrangement, a program must ensure family child care providers operate sufficient hours to meet the child care needs of families and not less than 1,380 hours per year.

(d) *Licensing requirements.* A family child-care provider must be licensed by the state, tribal, or local entity to provide services in their home or family-like setting. When state, tribal, or local requirements vary from Head Start requirements, the most stringent provision applies.

(e) *Child development specialist.* A program that offers the family child care option must provide a child development specialist to support family child care providers and ensure the provision of quality services at each family child care home. Child development specialists must:

(1) Conduct regular visits to each home, some of which are unannounced, not less than once every two weeks;

(2) Periodically verify compliance with either contract requirements or agency policy;

(3) Facilitate ongoing communication between program staff, family child care providers, and enrolled families; and,

(4) Provide recommendations for technical assistance and support the family child care provider in developing relationships with other child care professionals.

§ 1302.24 Locally-designed program option variations.

(a) *Waiver option.* Programs may request to operate a locally-designed program option, including a combination of program options, to better meet the unique needs of their communities or to demonstrate or test alternative approaches for providing program services. In order to operate a locally-designed program option, programs must seek a waiver as described in this section and must deliver the full range of services, consistent with § 1302.20(b), and demonstrate how any change to their program design is consistent with achieving program goals in subpart J of this part.

(b) *Request for approval.* A program's request to operate a locally-designed variation may be approved by the responsible HHS official through the end of a program's current grant or, if the request is submitted through a grant application for an upcoming project period, for the project period of the new award. Such approval may be revoked based on progress toward program goals as described in § 1302.102 and monitoring as described in § 1304.2.

(c) *Waiver requirements.* (1) The responsible HHS official may waive one or more of the requirements contained in § 1302.21(b), (c)(1)(i), and (c)(2)(iii) and (iv); § 1302.22(a) through (c); and § 1302.23(b) and (c), but may not waive ratios or group size for children under 24 months. Center-based locally-designed options must meet the minimums described in section 640(k)(1) of the Act for center-based programs.

(2) If the responsible HHS official determines a waiver of group size for center-based services would better meet

the needs of children and families in a community, the group size may not exceed the limits below:

(i) A group that serves children 24 to 36 months of age must have no more than ten children; and,

(ii) A group that serves predominantly three-year-old children must have no more than twenty children; and,

(iii) A group that serves predominantly four-year-old children must have no more than twenty-four children.

(3) If the responsible HHS official approves a waiver to allow a program to operate below the minimums described in § 1302.21(c)(2)(iii) or (iv), a program must meet the requirements described in § 1302.21(c)(2)(i), or in the case of a double session variation, a program must meet the requirements described in § 1302.21(c)(2)(ii).

(4) In order to receive a waiver under this section, a program must provide supporting evidence that demonstrates the locally-designed variation effectively supports appropriate development and progress in children's early learning outcomes.

(5) In order to receive a waiver of service duration, a program must meet the requirement in paragraph (c)(4) of this section, provide supporting evidence that it better meets the needs of parents than the applicable service duration minimums described in § 1302.21(c)(1) and (c)(2)(iii) and (iv), § 1302.22(c), or § 1302.23(c), and assess the effectiveness of the variation in supporting appropriate development and progress in children's early learning outcomes.

(d) *Transition from previously approved program options.* If, before November 7, 2016, a program was approved to operate a program option that is no longer allowable under §§ 1302.21 through 1302.23, a program may continue to operate that model until July 31, 2018.

Subpart C—Education and Child Development Program Services

§ 1302.30 Purpose.

All programs must provide high-quality early education and child development services, including for children with disabilities, that promote children's cognitive, social, and emotional growth for later success in school. A center-based or family child care program must embed responsive and effective teacher-child interactions. A home-based program must promote secure parent-child relationships and help parents provide high-quality early learning experiences. All programs must implement a research-based curriculum, and screening and assessment procedures that support individualization and growth in the areas of development described in the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* and support family engagement in children's learning and development. A program must deliver developmentally, culturally, and linguistically appropriate learning experiences in language, literacy, mathematics, social and emotional functioning, approaches to learning, science, physical skills, and creative arts. To deliver such high-quality early education and child development services, a center-based or family child care program must implement, at a minimum, the elements contained in §§ 1302.31 through 1302.34, and a home-based program must implement, at a minimum, the elements in §§ 1302.33 and 1302.35.

§ 1302.31 Teaching and the learning environment.

(a) *Teaching and the learning environment.* A center-based and family child care program must ensure teachers and other relevant staff provide responsive care, effective teaching, and an organized learning environment that promotes healthy development and children's skill growth aligned with the *Head Start Early Learning Outcomes Framework: Ages Birth to Five,* including for children with disabilities. A program must also support implementation of such environment with integration of regular and ongoing supervision and a system of individualized and ongoing professional development, as appropriate. This includes, at a minimum, the practices described in paragraphs (b) through (e) of this section.

(b) *Effective teaching practices.* (1) Teaching practices must:

(i) Emphasize nurturing and responsive practices, interactions, and environments that foster trust and emotional security; are communication and language rich; promote critical thinking and problem-solving; social, emotional, behavioral, and language development; provide supportive feedback for learning; motivate continued effort; and support all children's engagement in learning experiences and activities;

(ii) Focus on promoting growth in the developmental progressions described in the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* by aligning with and using the Framework and the curricula as described in § 1302.32 to direct planning of organized activities, schedules, lesson plans, and the implementation of high-quality early learning experiences that are responsive to and build upon each child's individual pattern of development and learning;

(iii) Integrate child assessment data in individual and group planning; and,

(iv) Include developmentally appropriate learning experiences in language, literacy, social and emotional development, math, science, social studies, creative arts, and physical development that are focused toward achieving progress outlined in the *Head Start Early Learning Outcomes Framework: Ages Birth to Five.*

(2) For dual language learners, a program must recognize bilingualism and biliteracy as strengths and implement research-based teaching practices that support their development. These practices must:

(i) For an infant or toddler dual language learner, include teaching practices that focus on the development of the home language, when there is a teacher with appropriate language competency, and experiences that expose the child to English;

(ii) For a preschool age dual language learner, include teaching practices that focus on both English language acquisition and the continued development of the home language; or,

(iii) If staff do not speak the home language of all children in the learning environment, include steps to support the development of the home language for dual language learners such as having culturally and linguistically appropriate materials available and other evidence-based strategies. Programs must work to identify volunteers who speak children's home language/s who could be trained to work in the classroom to support children's continued development of the home language.

(c) *Learning environment.* A program must ensure teachers implement well-organized learning environments with developmentally appropriate schedules, lesson plans, and indoor and outdoor learning experiences that provide adequate opportunities for choice, play, exploration, and experimentation among a variety of learning, sensory, and motor experiences and:

(1) For infants and toddlers, promote relational learning and include individualized and small group activities that integrate appropriate daily routines into a flexible schedule of learning experiences; and,

(2) For preschool age children, include teacher-directed and child-initiated activities, active and quiet learning activities, and opportunities for

individual, small group, and large group learning activities.

(d) *Materials and space for learning.* To support implementation of the curriculum and the requirements described in paragraphs (a), (b), (c), and (e) of this section a program must provide age-appropriate equipment, materials, supplies and physical space for indoor and outdoor learning environments, including functional space. The equipment, materials and supplies must include any necessary accommodations and the space must be accessible to children with disabilities. Programs must change materials intentionally and periodically to support children's interests, development, and learning.

(e) *Promoting learning through approaches to rest, meals, routines, and physical activity.* (1) A program must implement an intentional, age appropriate approach to accommodate children's need to nap or rest, and that, for preschool age children in a program that operates for 6 hours or longer per day provides a regular time every day at which preschool age children are encouraged but not forced to rest or nap. A program must provide alternative quiet learning activities for children who do not need or want to rest or nap.

(2) A program must implement snack and meal times in ways that support development and learning. For bottle-fed infants, this approach must include holding infants during feeding to support socialization. Snack and meal times must be structured and used as learning opportunities that support teaching staff-child interactions and foster communication and conversations that contribute to a child's learning, development, and socialization. Programs are encouraged to meet this requirement with family style meals when developmentally appropriate. A program must also provide sufficient time for children to eat, not use food as reward or punishment, and not force children to finish their food.

(3) A program must approach routines, such as hand washing and diapering, and transitions between activities, as opportunities for strengthening development, learning, and skill growth.

(4) A program must recognize physical activity as important to learning and integrate intentional movement and physical activity into curricular activities and daily routines in ways that support health and learning. A program must not use physical activity as reward or punishment.

§ 1302.32 Curricula.

(a) *Curricula.* (1) Center-based and family child care programs must implement developmentally appropriate research-based early childhood curricula, including additional curricular enhancements, as appropriate that:

(i) Are based on scientifically valid research and have standardized training procedures and curriculum materials to support implementation;

(ii) Are aligned with the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* and, as appropriate, state early learning and development standards; and are sufficiently content-rich to promote measurable progress toward development and learning outlined in the Framework; and,

(iii) Have an organized developmental scope and sequence that include plans and materials for learning experiences based on developmental progressions and how children learn.

(2) A program must support staff to effectively implement curricula and at a minimum monitor curriculum implementation and fidelity, and provide support, feedback, and supervision for continuous improvement of its implementation through the system of training and professional development.

(b) *Adaptation.* A program that chooses to make significant adaptations to a curriculum or a curriculum enhancement described in paragraph (a)(1) of this section to better meet the needs of one or more specific populations must use an external early childhood education curriculum or content area expert to develop such significant adaptations. A program must assess whether the adaptation adequately facilitates progress toward meeting school readiness goals, consistent with the process described in § 1302.102(b) and (c). Programs are encouraged to partner with outside evaluators in assessing such adaptations.

§ 1302.33 Child screenings and assessments.

(a) *Screening.* (1) In collaboration with each child's parent and with parental consent, a program must complete or obtain a current developmental screening to identify concerns regarding a child's developmental, behavioral, motor, language, social, cognitive, and emotional skills within 45 calendar days of when the child first attends the program or, for the home-based program option, receives a home visit. A program that operates for 90 days or less must complete or obtain a current developmental screening within 30 calendar days of when the child first attends the program.

(2) A program must use one or more research-based developmental standardized screening tools to complete the screening. A program must use as part of the screening additional information from family members, teachers, and relevant staff familiar with the child's typical behavior.

(3) If warranted through screening and additional relevant information and with direct guidance from a mental health or child development professional a program must, with the parent's consent, promptly and appropriately address any needs identified through:

(i) Referral to the local agency responsible for implementing IDEA for a formal evaluation to assess the child's eligibility for services under IDEA as soon as possible, and not to exceed timelines required under IDEA; and,

(ii) Partnership with the child's parents and the relevant local agency to support families through the formal evaluation process.

(4) If a child is determined to be eligible for services under IDEA, the program must partner with parents and the local agency responsible for implementing IDEA, as appropriate, and deliver the services in subpart F of this part.

(5) If, after the formal evaluation described in paragraph (a)(3)(i) of this section, the local agency responsible for implementing IDEA determines the child is not eligible for early intervention or special education and related services under IDEA, the program must:

(i) Seek guidance from a mental health or child development professional to determine if the formal evaluation shows the child has a significant delay in one or more areas of development that is likely to interfere with the child's development and school readiness; and,

(ii) If the child has a significant delay, partner with parents to help the family access services and supports to help address the child's identified needs.

(A) Such additional services and supports may be available through a child's health insurance or it may be appropriate for the program to provide needed services and supports under section 504 of the Rehabilitation Act if the child satisfies the definition of disability in 29 U.S.C. 705(9)(b) of the Rehabilitation Act, to ensure that the child who satisfies the definition of disability in 29 U.S.C. 705(9)(b) of the Rehabilitation Act is not excluded from the program on the basis of disability.

(B) A program may use program funds for such services and supports when no other sources of funding are available.

(b) *Assessment for individualization.* (1) A program must conduct standardized and structured assessments, which may be observation-based or direct, for each child that provide ongoing information to evaluate the child's developmental level and progress in outcomes aligned to the goals described in the *Head Start Early Learning Child Outcomes Framework: Ages Birth to Five.* Such assessments must result in usable information for teachers, home visitors, and parents and be conducted with sufficient frequency to allow for individualization within the program year.

(2) A program must regularly use information from paragraph (b)(1) of this section along with informal teacher observations and additional information from family and staff, as relevant, to determine a child's strengths and needs, inform and adjust strategies to better support individualized learning and improve teaching practices in center-based and family child care settings, and improve home visit strategies in home-based models.

(3) If warranted from the information gathered from paragraphs (b)(1) and (2) of this section and with direct guidance from a mental health or child development professional and a parent's consent, a program must refer the child to the local agency responsible for implementing IDEA for a formal evaluation to assess a child's eligibility for services under IDEA.

(c) *Characteristics of screenings and assessments.* (1) Screenings and assessments must be valid and reliable for the population and purpose for which they will be used, including by being conducted by qualified and trained personnel, and being age, developmentally, culturally and linguistically appropriate, and appropriate for children with disabilities, as needed.

(2) If a program serves a child who speaks a language other than English, a program must use qualified bilingual staff, contractor, or consultant to:

(i) Assess language skills in English and in the child's home language, to assess both the child's progress in the home language and in English language acquisition;

(ii) Conduct screenings and assessments for domains other than language skills in the language or languages that best capture the child's development and skills in the specific domain; and,

(iii) Ensure those conducting the screening or assessment know and understand the child's language and culture and have sufficient skill level in the child's home language to accurately administer the screening or assessment and to record and understand the child's responses, interactions, and communications.

(3) If a program serves a child who speaks a language other than English and qualified bilingual staff, contractors, or consultants are not able to conduct screenings and assessments, a program must use an interpreter in conjunction with a qualified staff person to conduct screenings and assessments as described in paragraphs (c)(2)(i) through (iii) of this section.

(4) If a program serves a child who speaks a language other than English and can demonstrate that there is not a qualified bilingual staff person or interpreter, then screenings and assessments may be conducted in English. In such a case, a program must also gather and use other information, including structured observations over time and information gathered in a child's home language from the family, for use in evaluating the child's development and progress.

(d) *Prohibitions on use of screening and assessment data.* The use of screening and assessment items and data on any screening or assessment authorized under this subchapter by any agent of the federal government is prohibited for the purposes of ranking, comparing, or otherwise evaluating individual children for purposes other than research, training, or technical assistance, and is prohibited for the purposes of providing rewards or sanctions for individual children or staff. A program must not use screening or assessments to exclude children from enrollment or participation.

§ 1302.34 Parent and family engagement in education and child development services.

(a) *Purpose.* Center-based and family child care programs must structure education and child development services to recognize parents' roles as children's lifelong educators, and to encourage parents to engage in their child's education.

(b) *Engaging parents and family members.* A program must offer opportunities for parents and family members to be involved in the program's education services and implement policies to ensure:

(1) The program's settings are open to parents during all program hours;

(2) Teachers regularly communicate with parents to ensure they are well-informed about their child's routines, activities, and behavior;

(3) Teachers hold parent conferences, as needed, but no less than two times per program year, to enhance the knowledge and understanding of both staff and parents of the child's education and developmental progress and activities in the program;

(4) Parents have the opportunity to learn about and to provide feedback on selected curricula and instructional materials used in the program;

(5) Parents and family members have opportunities to volunteer in the class and during group activities;

(6) Teachers inform parents, about the purposes of and the results from screenings and assessments and discuss their child's progress;

(7) Teachers, except those described in paragraph (b)(8) of this section, conduct at least two home visits per program year for each family, including one before the program year begins, if feasible, to engage the parents in the child's learning and development, except that such visits may take place at a program site or another safe location that affords privacy at the parent's request, or if a visit to the home presents significant safety hazards for staff; and,

(8) Teachers that serve migrant or seasonal families make every effort to conduct home visits to engage the family in the child's learning and development.

§ 1302.35 Education in home-based programs.

(a) *Purpose.* A home-based program must provide home visits and group socialization activities that promote secure parent-child relationships and help parents provide high-quality early learning experiences in language, literacy, mathematics, social and emotional functioning, approaches to learning, science, physical skills, and creative arts. A program must implement a research-based curriculum that delivers developmentally, linguistically, and culturally appropriate home visits and group socialization activities that support children's cognitive, social, and emotional growth for later success in school.

(b) *Home-based program design.* A home-based program must ensure all home visits are:

(1) Planned jointly by the home visitor and parents, and reflect the critical role of parents in the early learning and development of their children, including that the home visitor is able to effectively communicate with the parent, directly or through an interpreter;

(2) Planned using information from ongoing assessments that individualize learning experiences;

(3) Scheduled with sufficient time to serve all enrolled children in the home and conducted with parents and are not conducted when only babysitters or other temporary caregivers are present;

(4) Scheduled with sufficient time and appropriate staff to ensure effective delivery of services described in subparts D, E, F, and G of this part through home visiting, to the extent possible.

(c) *Home visit experiences.* A program that operates the home-based option must ensure all home visits focus on promoting high-quality early learning experiences in the home and growth towards the goals described in the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* and must use such goals and the curriculum to plan home visit activities that implement:

(1) Age and developmentally appropriate, structured child-focused learning experiences;

(2) Strategies and activities that promote parents' ability to support the child's cognitive, social, emotional, language, literacy, and physical development;

(3) Strategies and activities that promote the home as a learning environment that is safe, nurturing, responsive, and language- and communication- rich;

(4) Research-based strategies and activities for children who are dual language learners that recognize bilingualism and biliteracy as strengths, and:

(i) For infants and toddlers, focus on the development of the home language, while providing experiences that expose both parents and children to English; and,

(ii) For preschoolers, focus on both English language acquisition and the continued development of the home language; and,

(5) Follow-up with the families to discuss learning experiences provided in the home between each visit, address concerns, and inform strategies to promote progress toward school readiness goals.

(d) *Home-based curriculum.* A program that operates the home-based option must:

(1) Ensure home-visiting and group socializations implement a developmentally appropriate research-based early childhood home-based curriculum that:

(i) Promotes the parent's role as the child's teacher through experiences focused on the parent-child relationship and, as appropriate, the family's traditions, culture, values, and beliefs;

(ii) Aligns with the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* and, as appropriate, state early learning standards, and, is sufficiently content-rich within the Framework to promote measurable progress toward goals outlined in the Framework; and,

(iii) Has an organized developmental scope and sequence that includes plans and materials for learning experiences based on developmental progressions and how children learn.

(2) Support staff in the effective implementation of the curriculum and at a minimum monitor curriculum implementation and fidelity, and provide support, feedback, and supervision for continuous improvement of its implementation through the system of training and professional development.

(3) If a program chooses to make significant adaptations to a curriculum or curriculum enhancement to better meet the needs of one or more specific populations, a program must:

(i) Partner with early childhood education curriculum or content experts; and,

(ii) Assess whether the adaptation adequately facilitates progress toward meeting school readiness goals consistent with the process described in § 1302.102(b) and (c).

(4) Provide parents with an opportunity to review selected curricula and instructional materials used in the program.

(e) *Group socialization.* (1) A program that operates the home-based option must ensure group socializations are planned jointly with families, conducted with both child and parent participation, occur in a classroom, community facility, home or field trip setting, as appropriate.

(2) Group socializations must be structured to:

(i) Provide age appropriate activities for participating children that are intentionally aligned to school readiness goals, the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* and the home-based curriculum; and,

(ii) Encourage parents to share experiences related to their children's development with other parents in order to strengthen parent-child relationships and to help promote parents understanding of child development;

(3) For parents with preschoolers, group socializations also must provide opportunities for parents to participate in activities that support parenting skill development or family partnership goals identified in § 1302.52(c), as appropriate and must emphasize peer group interactions designed to promote children's social, emotional and language development, and progress towards school readiness goals, while encouraging parents to observe and actively participate in activities, as appropriate.

(f) *Screening and assessments.* A program that operates the home-based option must implement provisions in § 1302.33 and inform parents about the purposes of and the results from screenings and assessments and discuss their child's progress.

§ 1302.36 Tribal language preservation and revitalization.

A program that serves American Indian and Alaska Native children may integrate efforts to preserve, revitalize, restore, or maintain the tribal language for these children into program services. Such language preservation and revitalization efforts may include full immersion in the tribal language for the majority of the hours of planned class operations. If children's home language is English, exposure to English as described in § 1302.31(b)(2)(i) and (ii) is not required.

Subpart D—Health Program Services

§ 1302.40 Purpose.

(a) A program must provide high-quality health, oral health, mental health, and nutrition services that are developmentally, culturally, and linguistically appropriate and that will support each child's growth and school readiness.

(b) A program must establish and maintain a Health Services Advisory Committee that includes Head Start parents, professionals, and other volunteers from the community.

§ 1302.41 Collaboration and communication with parents.

(a) For all activities described in this part, programs must collaborate with parents as partners in the health and well-being of their children in a linguistically and culturally appropriate manner and communicate with parents about their child's health needs and development concerns in a timely and effective manner.

(b) At a minimum, a program must:

(1) Obtain advance authorization from the parent or other person with legal authority for all health and developmental procedures administered through the program or by contract or agreement, and, maintain written documentation if they refuse to give authorization for health services; and,

(2) Share with parents the policies for health emergencies that require rapid response on the part of staff or immediate medical attention.

§ 1302.42 Child health status and care.

(a) *Source of health care.* (1) A program, within 30 calendar days after the child first attends the program or, for the home-based program option, receives a home visit, must consult with parents to determine whether each child has ongoing sources of continuous, accessible health care—provided by a health care professional that maintains the child's ongoing health record and is not primarily a source of emergency or urgent care—and health insurance coverage.

(2) If the child does not have such a source of ongoing care and health insurance coverage or access to care through the Indian Health Service, the program must assist families in accessing a source of care and health insurance that will meet these criteria, as quickly as possible.

(b) *Ensuring up-to-date child health status.* (1) Within 90 calendar days after the child first attends the program or, for the home-based program option, receives a home visit, with the exceptions noted in paragraph (b)(3) of this section, a program must:

(i) Obtain determinations from health care and oral health care professionals as to whether or not the child is up-to-date on a schedule of age appropriate preventive and primary medical and oral health care, based on: The well-child visits and dental periodicity schedules as prescribed by the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program of the Medicaid agency of the state in which they operate, immunization recommendations issued by the Centers for Disease Control and Prevention, and any additional recommendations from the local Health Services Advisory Committee that are based on prevalent community health problems;

(ii) Assist parents with making arrangements to bring the child up-to-date as quickly as possible; and, if necessary, directly facilitate provision of health services to bring the child up-to-date with parent consent as described in § 1302.41(b)(1).

(2) Within 45 calendar days after the child first attends the program or, for the home-based program option, receives a home visit, a program must either obtain or perform evidence-based vision and hearing screenings.

(3) If a program operates for 90 days or less, it has 30 days from the date the child first attends the program to satisfy paragraphs (b)(1) and (2) of this section.

(4) A program must identify each child's nutritional health needs, taking into account available health information, including the child's health records, and family and staff concerns, including special dietary requirements, food allergies, and community nutrition issues as identified through the community assessment or by the Health Services Advisory Committee.

(c) *Ongoing care.* (1) A program must help parents continue to follow recommended schedules of well-child and oral health care.

(2) A program must implement periodic observations or other appropriate strategies for program staff and parents to identify any new or recurring developmental, medical, oral, or mental health concerns.

(3) A program must facilitate and monitor necessary oral health preventive care, treatment and follow-up, including topical fluoride treatments. In communities where there is a lack of adequate fluoride available through the water supply and for every child with moderate to severe tooth decay, a program must also facilitate fluoride supplements, and other necessary preventive measures, and further oral health treatment as recommended by the oral health professional.

(d) *Extended follow-up care.* (1) A program must facilitate further diagnostic testing, evaluation, treatment, and follow-up plan, as appropriate, by a licensed or certified professional for each child with a health problem or developmental delay, such as elevated lead levels or abnormal hearing or vision results that may affect child's development, learning, or behavior.

(2) A program must develop a system to track referrals and services provided and monitor the implementation of a follow-up plan to meet any treatment needs associated with a health, oral health, social and emotional, or developmental problem.

(3) A program must assist parents, as needed, in obtaining any prescribed medications, aids or equipment for medical and oral health conditions.

(e) *Use of funds.* (1) A program must use program funds for the provision of diapers and formula for enrolled children during the program day.

(2) A program may use program funds for professional medical and oral health services when no other source of funding is available. When program funds are used for such services, grantee and delegate agencies must have written documentation of their efforts to access other available sources of funding.

§ 1302.43 Oral health practices.

A program must promote effective oral health hygiene by ensuring all children with teeth are assisted by appropriate staff, or volunteers, if available, in brushing their teeth with toothpaste containing fluoride once daily.

§ 1302.44 Child nutrition.

(a) *Nutrition service requirements.* (1) A program must design and implement nutrition services that are culturally and developmentally appropriate, meet the nutritional needs of and accommodate the feeding requirements of each child, including children with special dietary needs and children with disabilities. Family style meals are encouraged as described in § 1302.31(e)(2).

(2) Specifically, a program must:

(i) Ensure each child in a program that operates for fewer than six hours per day receives meals and snacks that provide one third to one half of the child's daily nutritional needs;

(ii) Ensure each child in a program that operates for six hours or more per day receives meals and snacks that provide one half to two thirds of the child's daily nutritional needs, depending upon the length of the program day;

(iii) Serve three- to five-year-olds meals and snacks that conform to USDA requirements in 7 CFR parts 210, 220, and 226, and are high in nutrients and low in fat, sugar, and salt;

(iv) Feed infants and toddlers according to their individual developmental readiness and feeding skills as recommended in USDA requirements outlined in 7 CFR parts 210, 220, and 226, and ensure infants and young toddlers are fed on demand to the extent possible;

(v) Ensure bottle-fed infants are never laid down to sleep with a bottle;

(vi) Serve all children in morning center-based settings who have not received breakfast upon arrival at the program a nourishing breakfast;

(vii) Provide appropriate healthy snacks and meals to each child during group socialization activities in the home-based option;

(viii) Promote breastfeeding, including providing facilities to properly store and handle breast milk and make accommodations, as necessary, for mothers who wish to breastfeed during program hours, and if necessary, provide referrals to lactation consultants or counselors; and,

(ix) Make safe drinking water available to children during the program day.

(b) *Payment sources.* A program must use funds from USDA Food, Nutrition, and Consumer Services child nutrition programs as the primary source of payment for meal services. Early Head Start and Head Start funds may be used to cover those allowable costs not covered by the USDA.

§ 1302.45 Child mental health and social and emotional well-being.

(a) *Wellness promotion.* To support a program-wide culture that promotes children's mental health, social and emotional well-being, and overall health, a program must:

(1) Provide supports for effective classroom management and positive learning environments; supportive teacher practices; and, strategies for supporting children with challenging behaviors and other social, emotional, and mental health concerns;

(2) Secure mental health consultation services on a schedule of sufficient and consistent frequency to ensure a mental health consultant is available to partner with staff and families in a timely and effective manner;

(3) Obtain parental consent for mental health consultation services at enrollment; and,

(4) Build community partnerships to facilitate access to additional mental health resources and services, as needed.

(b) *Mental health consultants.* A program must ensure mental health consultants assist:

(1) The program to implement strategies to identify and support children with mental health and social and emotional concerns;

(2) Teachers, including family child care providers, to improve classroom management and teacher practices through strategies that include using classroom observations and consultations to address teacher and individual child needs and creating physical and cultural environments that promote positive mental health and social and emotional functioning;

(3) Other staff, including home visitors, to meet children's mental health and social and emotional needs through strategies that include observation and consultation;

(4) Staff to address prevalent child mental health concerns, including internalizing problems such as appearing withdrawn and externalizing problems such as challenging behaviors; and,

(5) In helping both parents and staff to understand mental health and access mental health interventions, if needed.

(6) In the implementation of the policies to limit suspension and prohibit expulsion as described in § 1302.17.

§ 1302.46 Family support services for health, nutrition, and mental health.

(a) *Parent collaboration.* Programs must collaborate with parents to promote children's health and well-being by providing medical, oral, nutrition and mental health education support services that are understandable to individuals, including individuals with low health literacy.

(b) *Opportunities.* (1) Such collaboration must include opportunities for parents to:

(i) Learn about preventive medical and oral health care, emergency first aid, environmental hazards, and health and safety practices for the home including health and developmental consequences of tobacco products use and exposure to lead, and safe sleep;

(ii) Discuss their child's nutritional status with staff, including the importance of physical activity, healthy eating, and the negative health consequences of sugar-sweetened beverages, and how to select and prepare nutritious foods that meet the family's nutrition and food budget needs;

(iii) Learn about healthy pregnancy and postpartum care, as appropriate, including breastfeeding support and treatment options for parental mental health or substance abuse problems, including perinatal depression;

(iv) Discuss with staff and identify issues related to child mental health and social and emotional well-being, including observations and any concerns about their child's mental health, typical and atypical behavior and development, and how to appropriately respond to their child and promote their child's social and emotional development; and,

(v) Learn about appropriate vehicle and pedestrian safety for keeping children safe.

(2) A program must provide ongoing support to assist parents' navigation through health systems to meet the general health and specifically identified needs of their children and must assist parents:

(i) In understanding how to access health insurance for themselves and their families, including information about private and public health insurance and designated enrollment periods;

(ii) In understanding the results of diagnostic and treatment procedures as well as plans for ongoing care; and,

(iii) In familiarizing their children with services they will receive while enrolled in the program and to enroll and participate in a system of ongoing family health care.

§ 1302.47 Safety practices.

(a) A program must establish, train staff on, implement, and enforce a system of health and safety practices that ensure children are kept safe at all times. A program should consult *Caring for our Children Basics,* available at *http://www.acf.hhs.gov/sites/default/files/ecd/caring_for_our_children_basics.pdf,* for additional information to develop and implement adequate safety policies and practices described in this part.

(b) A program must develop and implement a system of management, including ongoing training, oversight, correction and continuous improvement in accordance with § 1302.102, that includes policies and practices to ensure all facilities, equipment and materials, background checks, safety training, safety and hygiene practices and administrative safety procedures are adequate to ensure child safety. This system must ensure:

(1) *Facilities.* All facilities where children are served, including areas for learning, playing, sleeping, toileting, and eating are, at a minimum:

(i) Meet licensing requirements in accordance with §§ 1302.21(d)(1) and 1302.23(d);

(ii) Clean and free from pests;

(iii) Free from pollutants, hazards and toxins that are accessible to children and could endanger children's safety;

(iv) Designed to prevent child injury and free from hazards, including choking, strangulation, electrical, and drowning hazards, hazards posed by appliances and all other safety hazards;

(v) Well lit, including emergency lighting;

(vi) Equipped with safety supplies that are readily accessible to staff, including, at a minimum, fully-equipped and up-to-date first aid kits and appropriate fire safety supplies;

(vii) Free from firearms or other weapons that are accessible to children;

(viii) Designed to separate toileting and diapering areas from areas for preparing food, cooking, eating, or children's activities; and,

(ix) Kept safe through an ongoing system of preventative maintenance.

(2) *Equipment and materials.* Indoor and outdoor play equipment, cribs, cots, feeding chairs, strollers, and other equipment used in the care of enrolled children, and as applicable, other equipment and materials meet standards set by the Consumer Product Safety Commission (CPSC) or the American Society for Testing and Materials, International (ASTM). All equipment and materials must at a minimum:

(i) Be clean and safe for children's use and are appropriately disinfected;

(ii) Be accessible only to children for whom they are age appropriate;

(iii) Be designed to ensure appropriate supervision of children at all times;

(iv) Allow for the separation of infants and toddlers from preschoolers during play in center-based programs; and,

(v) Be kept safe through an ongoing system of preventative maintenance.

(3) *Background checks.* All staff have complete background checks in accordance with § 1302.90(b).

(4) *Safety training*—(i) *Staff with regular child contact.* All staff with regular child contact have initial orientation training within three months of hire and ongoing training in all state, local, tribal, federal and program-developed health, safety and child care requirements to ensure the safety of children in their care; including, at a minimum, and as appropriate based on staff roles and ages of children they work with, training in:

(A) The prevention and control of infectious diseases;

(B) Prevention of sudden infant death syndrome and use of safe sleeping practices;

(C) Administration of medication, consistent with standards for parental consent;

(D) Prevention and response to emergencies due to food and allergic reactions;

(E) Building and physical premises safety, including identification of and protection from hazards, bodies of water, and vehicular traffic;

(F) Prevention of shaken baby syndrome, abusive head trauma, and child maltreatment;

(G) Emergency preparedness and response planning for emergencies;

(H) Handling and storage of hazardous materials and the appropriate disposal of biocontaminants;

(I) Appropriate precautions in transporting children, if applicable;

(J) First aid and cardiopulmonary resuscitation; and,

(K) Recognition and reporting of child abuse and neglect, in accordance with the requirement at paragraph (b)(5) of this section.

(ii) *Staff without regular child contact.* All staff with no regular responsibility for or contact with children have initial orientation training within three months of hire; ongoing training in all state, local, tribal, federal and program-developed health and safety requirements applicable to their work; and training in the program's emergency and disaster preparedness procedures.

(5) *Safety practices.* All staff and consultants follow appropriate practices to keep children safe during all activities, including, at a minimum:

(i) Reporting of suspected or known child abuse and neglect, including that staff comply with applicable federal, state, local, and tribal laws;

(ii) Safe sleep practices, including ensuring that all sleeping arrangements for children under 18 months of age use firm mattresses or cots, as appropriate, and for children under 12 months, soft bedding materials or toys must not be used;

(iii) Appropriate indoor and outdoor supervision of children at all times;

(iv) Only releasing children to an authorized adult, and;

(v) All standards of conduct described in § 1302.90(c).

(6) *Hygiene practices.* All staff systematically and routinely implement hygiene practices that at a minimum ensure:

(i) Appropriate toileting, hand washing, and diapering procedures are followed;

(ii) Safe food preparation; and,

(iii) Exposure to blood and body fluids are handled consistent with standards of the Occupational Safety Health Administration.

(7) *Administrative safety procedures.* Programs establish, follow, and practice, as appropriate, procedures for, at a minimum:

(i) Emergencies;

(ii) Fire prevention and response;

(iii) Protection from contagious disease, including appropriate inclusion and exclusion policies for when a child is ill, and from an infectious disease outbreak, including appropriate notifications of any reportable illness;

(iv) The handling, storage, administration, and record of administration of medication;

(v) Maintaining procedures and systems to ensure children are only released to an authorized adult; and,

(vi) Child specific health care needs and food allergies that include accessible plans of action for emergencies. For food allergies, a program must also post individual child food allergies prominently where staff can view wherever food is served.

(8) *Disaster preparedness plan.* The program has all-hazards emergency management/disaster preparedness and response plans for more and less likely events including natural and manmade disasters and emergencies, and violence in or near programs.

(c) A program must report any safety incidents in accordance with § 1302.102(d)(1)(ii).

Subpart E—Family and Community Engagement Program Services

§ 1302.50 Family engagement.

(a) *Purpose.* A program must integrate parent and family engagement strategies into all systems and program services to support family well-being and promote children's learning and development. Programs are encouraged to develop innovative two-generation approaches that address prevalent needs of families across their program that may leverage community partnerships or other funding sources.

(b) *Family engagement approach.* A program must:

(1) Recognize parents as their children's primary teachers and nurturers and implement intentional strategies to engage parents in their children's learning and development and support parent-child relationships, including specific strategies for father engagement;

(2) Develop relationships with parents and structure services to encourage trust and respectful, ongoing two-way communication between staff and parents to create welcoming program environments that incorporate the unique cultural, ethnic, and linguistic backgrounds of families in the program and community;

(3) Collaborate with families in a family partnership process that identifies needs, interests, strengths, goals, and services and resources that support family well-being, including family safety, health, and economic stability;

(4) Provide parents with opportunities to participate in the program as employees or volunteers;

(5) Conduct family engagement services in the family's preferred language, or through an interpreter, to the extent possible, and ensure families have the opportunity to share personal information in an environment in which they feel safe; and,

(6) Implement procedures for teachers, home visitors, and family support staff to share information with each other, as appropriate and consistent with the requirements in part 1303, subpart C, of this chapter; FERPA; or IDEA, to ensure coordinated family engagement strategies with children and families in the classroom, home, and community.

§ 1302.51 Parent activities to promote child learning and development.

(a) A program must promote shared responsibility with parents for children's early learning and development, and implement family engagement strategies that are designed to foster parental confidence and skills in promoting children's learning and development. These strategies must include:

(1) Offering activities that support parent-child relationships and child development including language, dual language, literacy, and bi-literacy development as appropriate;

(2) Providing parents with information about the importance of their child's regular attendance, and partner with them, as necessary, to promote consistent attendance; and,

(3) For dual language learners, information and resources for parents about the benefits of bilingualism and biliteracy.

(b) A program must, at a minimum, offer opportunities for parents to participate in a research-based parenting curriculum that builds on parents' knowledge and offers parents the opportunity to practice parenting skills to promote children's learning and development. A program that chooses to make significant adaptations to the parenting curriculum to better meet the needs of one or more specific populations must work with an expert or experts to develop such adaptations.

§ 1302.52 Family partnership services.

(a) *Family partnership process.* A program must implement a family partnership process that includes a family partnership agreement and the activities described in this section to support family well-being, including family safety, health, and economic stability, to support child learning and development, to provide, if applicable, services and supports for children with disabilities, and to foster parental confidence and skills that promote the early learning and development of their children. The process must be initiated as early in the program year as possible and continue for as long as the family participates in the program, based on parent interest and need.

(b) *Identification of family strengths and needs.* A program must implement intake and family assessment procedures to identify family strengths and needs related to the family engagement outcomes as described in the Head Start Parent Family and Community Engagement Framework, including family well-being, parent-child relationships, families as lifelong educators, families as learners, family engagement in transitions, family connections to peers and the local community, and families as advocates and leaders.

(c) *Individualized family partnership services.* A program must offer individualized family partnership services that:

(1) Collaborate with families to identify interests, needs, and aspirations related to the family engagement outcomes described in paragraph (b) of this section;

(2) Help families achieve identified individualized family engagement outcomes;

(3) Establish and implement a family partnership agreement process that is jointly developed and shared with parents in which staff and families review individual progress, revise goals, evaluate and track whether identified needs and goals are met, and adjust strategies on an ongoing basis, as necessary, and;

(4) Assign staff and resources based on the urgency and intensity of identified family needs and goals.

(d) *Existing plans and community resources.* In implementing this section, a program must take into consideration any existing plans for the family made with other community agencies and availability of other community resources to address family needs, strengths, and goals, in order to avoid duplication of effort.

§ 1302.53 Community partnerships and coordination with other early childhood and education programs.

(a) *Community partnerships.* (1) A program must establish ongoing collaborative relationships and partnerships with community organizations such as establishing joint agreements, procedures, or contracts and arranging for onsite delivery of services as appropriate, to facilitate access to community services that are responsive to children's and families' needs and family partnership goals, and community needs and resources, as determined by the community assessment.

(2) A program must establish necessary collaborative relationships and partnerships, with community organizations that may include:

(i) Health care providers, including child and adult mental health professionals, Medicaid managed care networks, dentists, other health professionals, nutritional service providers, providers of prenatal and postnatal support, and substance abuse treatment providers;

(ii) Individuals and agencies that provide services to children with disabilities and their families, elementary schools, state preschool providers, and providers of child care services;

(iii) Family preservation and support services and child protective services and any other agency to which child abuse must be reported under state or tribal law;

(iv) Educational and cultural institutions, such as libraries and museums, for both children and families;

(v) Temporary Assistance for Needy Families, nutrition assistance agencies, workforce development and training programs, adult or family literacy, adult education, and post-secondary education institutions, and agencies or financial institutions that provide asset-building education, products and services to enhance family financial stability and savings;

(vi) Housing assistance agencies and providers of support for children and families experiencing homelessness, including the local educational agency liaison designated under section 722(g)(1)(J)(ii) of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11431 *et seq.*);

(vii) Domestic violence prevention and support providers; and,

(viii) Other organizations or businesses that may provide support and resources to families.

(b) *Coordination with other programs and systems.* A program must take an active role in promoting coordinated systems of comprehensive early childhood services to low-income children and families in their community through communication, cooperation, and the sharing of information among agencies and their community partners, while protecting the privacy of child records in accordance with subpart C of part 1303 of this chapter and applicable federal, state, local, and tribal laws.

(1) *Memorandum of understanding.* To support coordination between Head Start and publicly funded preschool programs, a program must enter into a memorandum of understanding with the appropriate local entity responsible for managing publicly funded preschool programs in the service area of the program, as described in section 642(e)(5) of the Act.

(2) *Quality Rating and Improvement Systems.* A program, with the exception of American Indian and Alaska Native programs, must participate in its state or local Quality Rating and Improvement System (QRIS) if:

(i) Its state or local QRIS accepts Head Start monitoring data to document quality indicators included in the state's tiered system;

(ii) Participation would not impact a program's ability to comply with the Head Start Program Performance Standards; and,

(iii) The program has not provided the Office of Head Start with a compelling reason not to comply with this requirement.

(3) *Data systems.* A program, with the exception of American Indian and Alaska Native programs unless they would like to and to the extent practicable, should integrate and share relevant data with state education data systems, to the extent practicable, if the program can receive similar support and benefits as other participating early childhood programs.

(4) *American Indian and Alaska Native programs.* An American Indian and Alaska Native program should determine whether or not it will participate in the systems described in paragraphs (b)(2) and (3) of this section.

Subpart F—Additional Services for Children With Disabilities

§ 1302.60 Full participation in program services and activities.

A program must ensure enrolled children with disabilities, including but not limited to those who are eligible for services under IDEA, and their families receive all applicable program services delivered in the least restrictive possible environment and that they fully participate in all program activities.

§ 1302.61 Additional services for children.

(a) *Additional services for children with disabilities.* Programs must ensure the individualized needs of children with disabilities, including but not limited to those eligible for services under IDEA, are being met and all children have access to and can fully participate in the full range of activities and services. Programs must provide any necessary modifications to the environment, multiple and varied formats for instruction, and individualized accommodations and supports as necessary to support the full participation of children with disabilities. Programs must ensure all individuals with disabilities are protected from discrimination under and provided with all services and program modifications required by section 504 of the Rehabilitation Act (29 U.S.C. 794), the Americans with Disabilities Act (42 U.S.C. 12101 *et seq.*), and their implementing regulations.

(b) *Services during IDEA eligibility determination.* While the local agency responsible for implementing IDEA determines a child's eligibility, a program must provide individualized services and supports, to the maximum extent possible, to meet the child's needs. Such additional supports may be available through a child's health insurance or it may be appropriate or required to provide the needed services and supports under section 504 of the Rehabilitation Act if the child satisfies the definition of disability in section 705(9)(b) of the Rehabilitation Act. When such supports are not available through alternate means, pending the evaluation results and eligibility determination, a program must individualize program services based on available information such as parent input and child observation and assessment data and may use program funds for these purposes.

(c) *Additional services for children with an IFSP or IEP.* To ensure the individual needs of children eligible for services under IDEA are met, a program must:

(1) Work closely with the local agency responsible for implementing IDEA, the family, and other service partners, as appropriate, to ensure:

(i) Services for a child with disabilities will be planned and delivered as required by their IFSP or IEP, as appropriate;

(ii) Children are working towards the goals in their IFSP or IEP;

(iii) Elements of the IFSP or IEP that the program cannot implement are implemented by other appropriate agencies, related service providers and specialists;

(iv) IFSPs and IEPs are being reviewed and revised, as required by IDEA; and,

(v) Services are provided in a child's regular Early Head Start or Head Start classroom or family child care home to the greatest extent possible.

(2) Plan and implement the transition services described in subpart G of this part, including at a minimum:

(i) For children with an IFSP who are transitioning out of Early Head Start, collaborate with the parents, and the local agency responsible for implementing IDEA, to ensure appropriate steps are undertaken in a timely and appropriate manner to determine the child's eligibility for services under Part B of IDEA; and,

(ii) For children with an IEP who are transitioning out of Head Start to kindergarten, collaborate with the parents, and the local agency responsible for implementing IDEA, to ensure steps are undertaken in a timely and appropriate manner to support the child and family as they transition to a new setting.

§ 1302.62 Additional services for parents.

(a) *Parents of all children with disabilities.* (1) A program must collaborate with parents of children with disabilities, including but not limited to children eligible for services under IDEA, to ensure the needs of their children are being met, including support to help parents become advocates for services that meet their children's needs and information and skills to help parents understand their child's disability and how to best support the child's development;

(2) A program must assist parents to access services and resources for their family, including securing adaptive equipment and devices and supports available through a child's health insurance or other entities, creating linkages to family support programs, and helping parents establish eligibility for additional support programs, as needed and practicable.

(b) *Parents of children eligible for services under IDEA.* For parents of children eligible for services under IDEA, a program must also help parents:

(1) Understand the referral, evaluation, and service timelines required under IDEA;

(2) Actively participate in the eligibility process and IFSP or IEP development process with the local agency responsible for implementing IDEA, including by informing parents of their right to invite the program to participate in all meetings;

(3) Understand the purposes and results of evaluations and services provided under an IFSP or IEP; and,

(4) Ensure their children's needs are accurately identified in, and addressed through, the IFSP or IEP.

§ 1302.63 Coordination and collaboration with the local agency responsible for implementing IDEA.

(a) A program must coordinate with the local agency responsible for implementing IDEA to identify children enrolled or who intend to enroll in a program that may be eligible for services under IDEA, including through the process described in § 1302.33(a)(3) and through participation in the local agency Child Find efforts.

(b) A program must work to develop interagency agreements with the local agency responsible for implementing IDEA to improve service delivery to children eligible for services under IDEA, including the referral and evaluation process, service coordination, promotion of service provision in the least restrictive appropriate community-based setting and reduction in dual enrollment which causes reduced time in a less restrictive setting, and transition services as children move from services provided under Part C of IDEA to services provided under Part B of IDEA and from preschool to kindergarten.

(c) A program must participate in the development of the IFSP or IEP if requested by the child's parents, and the implementation of the IFSP or IEP. At a minimum, the program must offer:

(1) To provide relevant information from its screenings, assessments, and observations to the team developing a child's IFSP or IEP; and,

(2) To participate in meetings with the local agency responsible for implementing IDEA to develop or review an IEP or IFSP for a child being considered for Head Start enrollment, a currently enrolled child, or a child transitioning from a program.

(d) A program must retain a copy of the IEP or IFSP for any child enrolled in Head Start for the time the child is in the program, consistent with the IDEA requirements in 34 CFR parts 300 and 303.

Subpart G—Transition Services

§ 1302.70 Transitions from Early Head Start.

(a) *Implementing transition strategies and practices.* An Early Head Start program must implement strategies and practices to support successful transitions for children and their families transitioning out of Early Head Start.

(b) *Timing for transitions.* To ensure the most appropriate placement and service following participation in Early Head Start, such programs must, at least six months prior to each child's third birthday, implement transition planning for each child and family that:

(1) Takes into account the child's developmental level and health and disability status, progress made by the child and family while in Early Head Start, current and changing family circumstances and, the availability of Head Start, other public pre-kindergarten, and other early education and child development services in the community that will meet the needs of the child and family; and,

(2) Transitions the child into Head Start or another program as soon as possible after the child's third birthday but permits the child to remain in Early Head Start for a limited number of additional months following the child's third birthday if necessary for an appropriate transition.

(c) *Family collaborations.* A program must collaborate with parents of Early Head Start children to implement strategies and activities that support successful transitions from Early Head Start and, at a minimum, provide information about the child's progress during the program year and provide strategies for parents to continue their involvement in and advocacy for the education and development of their child.

(d) *Early Head Start and Head Start collaboration.* Early Head Start and Head Start programs must work together to maximize enrollment transitions from Early Head Start to Head Start, consistent with the eligibility provisions in subpart A, and promote successful transitions through collaboration and communication.

(e) *Transition services for children with an IFSP.* A program must provide additional transition services for children with an IFSP, at a minimum, as described in subpart F of this part.

§ 1302.71 Transitions from Head Start to kindergarten.

(a) *Implementing transition strategies and practices.* A program that serves children who will enter kindergarten in the following year must implement transition strategies to support a successful transition to kindergarten.

(b) *Family collaborations for transitions.* (1) A program must collaborate with parents of enrolled children to implement strategies and activities that will help parents advocate for and promote successful transitions to kindergarten for their children, including their continued involvement in the education and development of their child.

(2) At a minimum, such strategies and activities must:

(i) Help parents understand their child's progress during Head Start;

(ii) Help parents understand practices they use to effectively provide academic and social support for their children during their transition to kindergarten and foster their continued involvement in the education of their child;

(iii) Prepare parents to exercise their rights and responsibilities concerning the education of their children in the elementary school setting, including services and supports available to children with disabilities and various options for their child to participate in language instruction educational programs; and,

(iv) Assist parents in the ongoing communication with teachers and other school personnel so that parents can participate in decisions related to their children's education.

(c) *Community collaborations for transitions.* (1) A program must collaborate with local education agencies to support family engagement under section 642(b)(13) of the Act and state departments of education, as appropriate, and kindergarten teachers to implement strategies and activities that promote successful transitions to kindergarten for children, their families, and the elementary school.

(2) At a minimum, such strategies and activities must include:

(i) Coordination with schools or other appropriate agencies to ensure children's relevant records are transferred to the school or next placement in which a child will enroll, consistent with privacy requirements in subpart C of part 1303 of this chapter;

(ii) Communication between appropriate staff and their counterparts in the schools to facilitate continuity of learning and development, consistent with privacy requirements in subpart C of part 1303 of this chapter; and,

(iii) Participation, as possible, for joint training and professional development activities for Head Start and kindergarten teachers and staff.

(3) A program that does not operate during the summer must collaborate with school districts to determine the availability of summer school programming for children who will be entering kindergarten and work with parents and school districts to enroll children in such programs, as appropriate.

(d) *Learning environment activities.* A program must implement strategies and activities in the learning environment that promote successful transitions to kindergarten for enrolled children, and at a minimum, include approaches that familiarize children with the transition to kindergarten and foster confidence about such transition.

(e) *Transition services for children with an IEP.* A program must provide additional transition services for children with an IEP, at a minimum, as described in subpart F of this part.

§ 1302.72 Transitions between programs.

(a) For families and children who move out of the community in which they are currently served, including homeless families and foster children, a program must undertake efforts to support effective transitions to other Early Head Start or Head Start programs. If Early Head Start or Head Start is not available, the program should assist the family to identify another early childhood program that meets their needs.

(b) A program that serves children whose families have decided to transition them to other early education programs, including public pre-kindergarten, in the year prior to kindergarten entry must undertake strategies and activities described in § 1302.71(b) and (c)(1) and (2), as practicable and appropriate.

(c) A migrant or seasonal Head Start program must undertake efforts to support effective transitions to other migrant or seasonal Head Start or, if appropriate, Early Head Start or Head Start programs for families and children moving out of the community in which they are currently served.

Subpart H—Services to Enrolled Pregnant Women

§ 1302.80 Enrolled pregnant women.

(a) Within 30 days of enrollment, a program must determine whether each enrolled pregnant woman has an ongoing source of continuous, accessible health care—provided by a health care professional that maintains her ongoing health record and is not primarily a source of emergency or urgent care—and, as appropriate, health insurance coverage.

(b) If an enrolled pregnant woman does not have a source of ongoing care as described in paragraph (a) of this section and, as appropriate, health insurance coverage, a program must, as quickly as possible, facilitate her access to such a source of care that will meet her needs.

(c) A program must facilitate the ability of all enrolled pregnant women to access comprehensive services through referrals that, at a minimum, include nutritional counseling, food assistance, oral health care, mental health services, substance abuse prevention and treatment, and emergency shelter or transitional housing in cases of domestic violence.

(d) A program must provide a newborn visit with each mother and baby to offer support and identify family needs. A program must schedule the newborn visit within two weeks after the infant's birth.

§ 1302.81 Prenatal and postpartum information, education, and services.

(a) A program must provide enrolled pregnant women, fathers, and partners or other relevant family members the prenatal and postpartum information, education and services that address, as appropriate, fetal development, the importance of nutrition, the risks of alcohol, drugs, and smoking, labor and delivery, postpartum recovery, parental depression, infant care and safe sleep practices, and the benefits of breastfeeding.

(b) A program must also address needs for appropriate supports for emotional well-being, nurturing and responsive caregiving, and father engagement during pregnancy and early childhood.

§ 1302.82 Family partnership services for enrolled pregnant women.

(a) A program must engage enrolled pregnant women and other relevant family members, such as fathers, in the family partnership services as described in § 1302.52 and include a specific focus on factors that influence prenatal and postpartum maternal and infant health.

(b) A program must engage enrolled pregnant women and other relevant family members, such as fathers, in discussions about program options, plan for the infant's transition to program enrollment, and support the family during the transition process, where appropriate.

Subpart I—Human Resources Management

§ 1302.90 Personnel policies.

(a) *Establishing personnel policies and procedures.* A program must establish written personnel policies and procedures that are approved by the governing body and policy council or policy committee and that are available to all staff.

(b) *Background checks and selection procedures.* (1) Before a person is hired, directly or through contract, including transportation staff and contractors, a program must conduct an interview, verify references, conduct a sex offender registry check and obtain one of the following:

(i) State or tribal criminal history records, including fingerprint checks; or,

(ii) Federal Bureau of Investigation criminal history records, including fingerprint checks.

(2) A program has 90 days after an employee is hired to complete the background check process by obtaining:

(i) Whichever check listed in paragraph (b)(1) of this section was not obtained prior to the date of hire; and,

(ii) Child abuse and neglect state registry check, if available.

(3) A program must review the information found in each employment application and complete background check to assess the relevancy of any issue uncovered by the complete background check including any arrest, pending criminal charge, or conviction and must use Child Care and Development Fund (CCDF) disqualification factors described in 42 U.S.C. 9858f(c)(1)(D) and 42 U.S.C. 9858f(h)(1) or tribal disqualifications factors to determine whether the prospective employee can be hired or the current employee must be terminated.

(4) A program must ensure a newly hired employee, consultant, or contractor does not have unsupervised access to children until the complete background check process described in paragraphs (b)(1) through (3) of this section is complete.

(5) A program must conduct the complete background check for each employee, consultant, or contractor at least once every five years which must include each of the four checks listed in paragraphs (b)(1) and (2) of this section, and review and make employment decisions based on the information as described in paragraph (b)(3) of this section, unless the program can demonstrate to the responsible HHS official that it has a more stringent system in place that will ensure child safety.

(6) A program must consider current and former program parents for employment vacancies for which such parents apply and are qualified.

(c) *Standards of conduct.* (1) A program must ensure all staff, consultants, contractors, and volunteers abide by the program's standards of conduct that:

(i) Ensure staff, consultants, contractors, and volunteers implement positive strategies to support children's well-being and prevent and address challenging behavior;

(ii) Ensure staff, consultants, contractors, and volunteers do not maltreat or endanger the health or safety of children, including, at a minimum, that staff must not:

(A) Use corporal punishment;

(B) Use isolation to discipline a child;

(C) Bind or tie a child to restrict movement or tape a child's mouth;

(D) Use or withhold food as a punishment or reward;

(E) Use toilet learning/training methods that punish, demean, or humiliate a child;

(F) Use any form of emotional abuse, including public or private humiliation, rejecting, terrorizing, extended ignoring, or corrupting a child;

(G) Physically abuse a child;

(H) Use any form of verbal abuse, including profane, sarcastic language, threats, or derogatory remarks about the child or child's family; or,

(I) Use physical activity or outdoor time as a punishment or reward;

(iii) Ensure staff, consultants, contractors, and volunteers respect and promote the unique identity of each child and family and do not stereotype on any basis, including gender, race, ethnicity, culture, religion, disability, sexual orientation, or family composition;

(iv) Require staff, consultants, contractors, and volunteers to comply with program confidentiality policies concerning personally identifiable information about children, families, and other staff members in accordance with subpart C of part 1303 of this chapter and applicable federal, state, local, and tribal laws; and,

(v) Ensure no child is left alone or unsupervised by staff, consultants, contractors, or volunteers while under their care.

(2) Personnel policies and procedures must include appropriate penalties for staff, consultants, and volunteers who violate the standards of conduct.

(d) *Communication with dual language learners and their families.* (1) A program must ensure staff and program consultants or contractors are familiar with the ethnic backgrounds and heritages of families in the program and are able to serve and effectively communicate, either directly or through interpretation and translation, with children who are dual language learners and to the extent feasible, with families with limited English proficiency.

(2) If a majority of children in a class or home-based program speak the same language, at least one class staff member or home visitor must speak such language.

§ 1302.91 Staff qualifications and competency requirements.

(a) *Purpose.* A program must ensure all staff, consultants, and contractors engaged in the delivery of program services have sufficient knowledge, training and experience, and competencies to fulfill the roles and responsibilities of their positions and to ensure high-quality service delivery in accordance with the program performance standards. A program must provide ongoing training and professional development to support staff in fulfilling their roles and responsibilities.

(b) *Early Head Start or Head Start director.* A program must ensure an Early Head Start or Head Start director hired after November 7, 2016, has, at a minimum, a baccalaureate degree and experience in supervision of staff, fiscal management, and administration.

(c) *Fiscal officer.* A program must assess staffing needs in consideration of the fiscal complexity of the organization and applicable financial management requirements and secure the regularly scheduled or ongoing services of a fiscal officer with sufficient education and experience to meet their needs. A program must ensure a fiscal officer hired after November 7, 2016, is a certified public accountant or has, at a minimum, a baccalaureate degree in accounting, business, fiscal management, or a related field.

(d) *Child and family services management staff qualification requirements*—(1) *Family, health, and disabilities management.* A program must ensure staff responsible for management and oversight of family services, health services, and services to children with disabilities hired after November 7, 2016, have, at a minimum, a baccalaureate degree, preferably related to one or more of the disciplines they oversee.

(2) *Education management.* As prescribed in section 648A(a)(2)(B)(i) of the Act, a program must ensure staff and consultants that serve as education managers or coordinators, including those that serve as curriculum specialists, have a baccalaureate or advanced degree in early childhood education or a baccalaureate or advanced degree and equivalent coursework in early childhood education with early education teaching experience.

(e) *Child and family services staff*—(1) *Early Head Start center-based teacher qualification requirements.* As prescribed in section 645A(h) of the Act, a program must ensure center-based teachers that provide direct services to infants and toddlers in Early Head Start centers have a minimum of a Child Development Associate (CDA) credential or comparable credential, and have been trained or have equivalent coursework in early childhood development with a focus on infant and toddler development.

(2) *Head Start center-based teacher qualification requirements.* (i) The Secretary must ensure no less than fifty percent of all Head Start teachers, nationwide, have a baccalaureate degree in child development, early childhood education, or equivalent coursework.

(ii) As prescribed in section 648A(a)(3)(B) of the Act, a program must ensure all center-based teachers have at least an associate's or bachelor's degree in child development or early childhood education, equivalent coursework, or otherwise meet the requirements of section 648A(a)(3)(B) of the Act.

(3) *Head Start assistant teacher qualification requirements.* As prescribed in section 648A(a)(2)(B)(ii) of the Act, a program must ensure Head Start assistant teachers, at a minimum, have a CDA credential or a state-awarded certificate that meets or exceeds the requirements for a CDA credential, are enrolled in a program that will lead to an associate or baccalaureate degree or, are enrolled in a CDA credential program to be completed within two years of the time of hire.

(4) *Family child care provider qualification requirements.* (i) A program must ensure family child care providers have previous early child care experience and, at a minimum, are enrolled in a Family Child Care CDA program or state equivalent, or an associate's or baccalaureate degree program in child development or early childhood education prior to beginning service provision, and for the credential acquire it within eighteen months of beginning to provide services.

(ii) By August 1, 2018, a child development specialist, as required for family child care in § 1302.23(e), must have, at a minimum, a baccalaureate degree in child development, early childhood education, or a related field.

(5) *Center-based teachers, assistant teachers, and family child care provider competencies.* A program must ensure center-based teachers, assistant teachers, and family child care providers demonstrate competency to provide effective and nurturing teacher-child interactions, plan and implement learning experiences that ensure effective curriculum implementation and use of assessment and promote children's progress across the standards described in the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* and applicable state early learning and development standards, including for children with disabilities and dual language learners, as appropriate.

(6) *Home visitors.* A program must ensure home visitors providing home-based education services:

(i) Have a minimum of a home-based CDA credential or comparable credential, or equivalent coursework as part of an associate's or bachelor's degree; and,

(ii) Demonstrate competency to plan and implement home-based learning experiences that ensure effective implementation of the home visiting curriculum and promote children's progress across the standards described in the *Head Start Early Learning Outcomes Framework: Ages Birth to Five,* including for children with disabilities and dual language learners, as appropriate, and to build respectful, culturally responsive, and trusting relationships with families.

(7) *Family services staff qualification requirements.* A program must ensure staff who work directly with families on the family partnership process hired after November 7, 2016, have within eighteen months of hire, at a minimum, a credential or certification in social work, human services, family services, counseling or a related field.

(8) *Health professional qualification requirements.* (i) A program must ensure health procedures are performed only by a licensed or certified health professional.

(ii) A program must ensure all mental health consultants are licensed or certified mental health professionals. A program must use mental health consultants with knowledge of and experience in serving young children and their families, if available in the community.

(iii) A program must use staff or consultants to support nutrition services who are registered dieticians or nutritionists with appropriate qualifications.

(f) *Coaches.* A program must ensure coaches providing the services described in § 1302.92(c) have a minimum of a baccalaureate degree in early childhood education or a related field.

§ 1302.92 Training and professional development.

(a) A program must provide to all new staff, consultants, and volunteers an orientation that focuses on, at a minimum, the goals and underlying philosophy of the program and on the ways they are implemented.

(b) A program must establish and implement a systematic approach to staff training and professional development designed to assist staff in acquiring or increasing the knowledge and skills needed to provide high-quality, comprehensive services within the scope of their job responsibilities, and attached to academic credit as appropriate. At a minimum, the system must include:

(1) Staff completing a minimum of 15 clock hours of professional development per year. For teaching staff, such professional development must meet the requirements described in section 648A(a)(5) of the Act.

(2) Training on methods to handle suspected or known child abuse and neglect cases, that comply with applicable federal, state, local, and tribal laws;

(3) Training for child and family services staff on best practices for implementing family engagement strategies in a systemic way, as described throughout this part;

(4) Training for child and family services staff, including staff that work on family services, health, and disabilities, that builds their knowledge, experience, and competencies to improve child and family outcomes; and,

(5) Research-based approaches to professional development for education staff, that are focused on effective curricula implementation, knowledge of the content in *Head Start Early Learning Outcomes Framework: Ages Birth to Five,* partnering with families, supporting children with disabilities and their families, providing effective and nurturing adult-child interactions, supporting dual language learners as appropriate, addressing challenging behaviors, preparing children and families for transitions (as described in subpart G of this part), and use of data to individualize learning experiences to improve outcomes for all children.

(c) A program must implement a research-based, coordinated coaching strategy for education staff that:

(1) Assesses all education staff to identify strengths, areas of needed support, and which staff would benefit most from intensive coaching;

(2) At a minimum, provides opportunities for intensive coaching to those education staff identified through the process in paragraph (c)(1) of this section, including opportunities to be observed and receive feedback and modeling of effective teacher practices directly related to program performance goals;

(3) At a minimum, provides opportunities for education staff not identified for intensive coaching through the process in paragraph (c)(1) of this section to receive other forms of research-based professional development aligned with program performance goals;

(4) Ensures intensive coaching opportunities for the staff identified through the process in paragraph (c)(1) of this section that:

(i) Align with the program's school readiness goals, curricula, and other approaches to professional development;

(ii) Utilize a coach with adequate training and experience in adult learning and in using assessment data to drive coaching strategies aligned with program performance goals;

(iii) Provide ongoing communication between the coach, program director, education director, and any other relevant staff; and,

(iv) Include clearly articulated goals informed by the program's goals, as described in § 1302.102, and a process for achieving those goals; and,

(5) Establishes policies that ensure assessment results are not used to solely determine punitive actions for staff identified as needing support, without providing time and resources for staff to improve.

(d) If a program needs to develop or significantly adapt their approach to research-based professional development to better meet the training needs of education staff, such that it does not include the requirements in paragraph (c) of this section, the program must partner with external early childhood education professional development experts. A program must assess whether the adaptation adequately supports staff professional development, consistent with the process laid out in subpart J of this part.

§ 1302.93 Staff health and wellness.

(a) A program must ensure each staff member has an initial health examination and a periodic re-examination as recommended by their health care provider in accordance with state, tribal, or local requirements, that include screeners or tests for communicable diseases, as appropriate. The program must ensure staff do not, because of communicable diseases, pose a significant risk to the health or safety of others in the program that cannot be eliminated or reduced by reasonable accommodation, in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

(b) A program must make mental health and wellness information available to staff regarding health issues that may affect their job performance, and must provide regularly scheduled opportunities to learn about mental health, wellness, and health education.

§ 1302.94 Volunteers.

(a) A program must ensure regular volunteers have been screened for appropriate communicable diseases in accordance with state, tribal or local laws. In the absence of state, tribal or local law, the Health Services Advisory Committee must be consulted regarding the need for such screenings.

(b) A program must ensure children are never left alone with volunteers.

Subpart J—Program Management and Quality Improvement

§ 1302.100 Purpose.

A program must provide management and a process of ongoing monitoring and continuous improvement for achieving program goals that ensures child safety and the delivery of effective, high-quality program services.

§ 1302.101 Management system.

(a) *Implementation.* A program must implement a management system that:

(1) Ensures a program, fiscal, and human resource management structure that provides effective management and oversight of all program areas and fiduciary responsibilities to enable delivery of high-quality services in all of

the program services described in subparts C, D, E, F, G, and H of this part;

(2) Provides regular and ongoing supervision to support individual staff professional development and continuous program quality improvement;

(3) Ensures budget and staffing patterns that promote continuity of care for all children enrolled, allow sufficient time for staff to participate in appropriate training and professional development, and allow for provision of the full range of services described in subparts C, D, E, F, G, and H of this part; and,

(4) Maintains an automated accounting and record keeping system adequate for effective oversight.

(b) *Coordinated approaches.* At the beginning of each program year, and on an ongoing basis throughout the year, a program must design and implement program-wide coordinated approaches that ensure:

(1) The training and professional development system, as described in § 1302.92, effectively supports the delivery and continuous improvement of high-quality services;

(2) The full and effective participation of children who are dual language learners and their families, by:

(i) Utilizing information from the program's community assessment about the languages spoken throughout the program service area to anticipate child and family needs;

(ii) Identifying community resources and establishing ongoing collaborative relationships and partnerships with community organizations consistent with the requirements in § 1302.53(a); and,

(iii) Systematically and comprehensively addressing child and family needs by facilitating meaningful access to program services, including, at a minimum, curriculum, instruction, staffing, supervision, and family partnerships with bilingual staff, oral language assistance and interpretation, or translation of essential program materials, as appropriate.

(3) The full and effective participation of all children with disabilities, including but not limited to children eligible for services under IDEA, by providing services with appropriate facilities, program materials, curriculum, instruction, staffing, supervision, and partnerships, at a minimum, consistent with section 504 of the Rehabilitation Act and the Americans with Disabilities Act; and,

(4) The management of program data to effectively support the availability, usability, integrity, and security of data. A program must establish procedures on data management, and have them approved by the governing body and policy council, in areas such as quality of data and effective use and sharing of data, while protecting the privacy of child records in accordance with subpart C of part 1303 of this chapter and applicable federal, state, local, and tribal laws.

§ 1302.102 Achieving program goals.

(a) *Establishing program goals.* A program, in collaboration with the governing body and policy council, must establish goals and measurable objectives that include:

(1) Strategic long-term goals for ensuring programs are and remain responsive to community needs as identified in their community assessment as described in subpart A of this part;

(2) Goals for the provision of educational, health, nutritional, and family and community engagement program services as described in the program performance standards to further promote the school readiness of enrolled children;

(3) School readiness goals that are aligned with the *Head Start Early Learning Outcomes Framework: Ages Birth to Five,* state and tribal early learning standards, as appropriate, and requirements and expectations of schools Head Start children will attend, per the requirements of subpart B of part 1304 of this part; and,

(4) Effective health and safety practices to ensure children are safe at all times, per the requirements in §§ 1302.47, 1302.90(b) and (c), 1302.92(c)(1), and 1302.94 and part 1303, subpart F, of this chapter.

(b) *Monitoring program performance*—(1) *Ongoing compliance oversight and correction.* In order to ensure effective ongoing oversight and correction, a program must establish and implement a system of ongoing oversight that ensures effective implementation of the program performance standards, including ensuring child safety, and other applicable federal regulations as described in this part, and must:

(i) Collect and use data to inform this process;

(ii) Correct quality and compliance issues immediately, or as quickly as possible;

(iii) Work with the governing body and the policy council to address issues during the ongoing oversight and correction process and during federal oversight; and,

(iv) Implement procedures that prevent recurrence of previous quality and compliance issues, including previously identified deficiencies, safety incidents, and audit findings.

(2) *Ongoing assessment of program goals.* A program must effectively oversee progress towards program goals on an ongoing basis and annually must:

(i) Conduct a self-assessment that uses program data including aggregated child assessment data, and professional development and parent and family engagement data as appropriate, to evaluate the program's progress towards meeting goals established under paragraph (a) of this section, compliance with program performance standards throughout the program year, and the effectiveness of the professional development and family engagement systems in promoting school readiness;

(ii) Communicate and collaborate with the governing body and policy council, program staff, and parents of enrolled children when conducting the annual self-assessment; and,

(iii) Submit findings of the self-assessment, including information listed in paragraph (b)(2)(i) of this section to the responsible HHS official.

(c) *Using data for continuous improvement.* (1) A program must implement a process for using data to identify program strengths and needs, develop and implement plans that address program needs, and continually evaluate compliance with program performance standards and progress towards achieving program goals described in paragraph (a) of this section.

(2) This process must:

(i) Ensure data is aggregated, analyzed and compared in such a way to assist agencies in identifying risks and informing strategies for continuous improvement in all program service areas;

(ii) Ensure child-level assessment data is aggregated and analyzed at least three times a year, including for sub-groups, such as dual language learners and children with disabilities, as appropriate, except in programs operating fewer than 90 days, and used with other program data described in paragraph (c)(2)(iv) of this section to direct continuous improvement related to curriculum choice and implementation, teaching practices, professional development, program design and other program decisions, including changing or targeting scope of services; and,

(iii) For programs operating fewer than 90 days, ensures child assessment data is aggregated and analyzed at least twice during the program operating period, including for subgroups, such as dual language learners and children with disabilities, as appropriate, and used with other program data described in paragraph (c)(2)(iv) of this section to direct continuous improvement related to curriculum choice and implementation, teaching practices, professional development, program design and other program decisions, including changing or targeting scope of services;

(iv) Use information from ongoing monitoring and the annual self-assessment, and program data on teaching practice, staffing and professional development, child-level assessments, family needs assessments, and comprehensive services, to identify program needs, and develop and implement plans for program improvement; and,

(v) Use program improvement plans as needed to either strengthen or adjust content and strategies for professional development, change program scope and services, refine school readiness and other program goals, and adapt strategies to better address the needs of sub-groups.

(d) *Reporting.* (1) A program must submit:

(i) Status reports, determined by ongoing oversight data, to the governing body and policy council, at least semi-annually;

(ii) Reports, as appropriate, to the responsible HHS official immediately or as soon as practicable, related to any significant incidents affecting the health and safety of program participants, circumstances affecting the financial viability of the program, breaches of personally identifiable information, or program involvement in legal proceedings, any matter for which notification or a report to state, tribal, or local authorities is required by applicable law, including at a minimum:

(A) Any reports regarding agency staff or volunteer compliance with federal, state, tribal, or local laws addressing child abuse and neglect or laws governing sex offenders;

(B) Incidents that require classrooms or centers to be closed for any reason;

(C) Legal proceedings by any party that are directly related to program operations; and,

(D) All conditions required to be reported under § 1304.12, including disqualification from the Child and Adult Care Food Program (CACFP) and license revocation.

(2) Annually, a program must publish and disseminate a report that complies with section 644(a)(2) of the Act and includes a summary of a program's most recent community assessment, as described in § 1302.11(b), consistent with privacy protections in subpart C of part 1303 of this chapter.

(3) If a program has had a deficiency identified, it must submit, to the responsible HHS official, a quality improvement plan as required in section 641A(e)(2) of the Act.

§ 1302.103 Implementation of program performance standards.

(a) A current program as of November 7, 2016, must implement a program-wide approach for the effective and timely implementation of the changes to the program performance standards, including the purchase of materials and allocation of staff time, as appropriate.

(b) A program's approach to implement the changes included in parts 1301 through 1304 of this chapter must ensure adequate preparation for effective and timely service delivery to children and their families including, at a minimum, review of community assessment data to determine the most appropriate strategy for implementing required program changes, including assessing any changes in the number of children who can be served, as necessary, the purchase of and training on any curriculum, assessment, or other materials, as needed, assessment of program-wide professional development needs, assessment of staffing patterns, the development of coordinated approaches described in § 1302.101(b), and the development of appropriate protections for data sharing; and children enrolled in the program on November 7, 2016 are not displaced during a program year and that children leaving Early Head Start or Head Start at the end of the program year following November 7, 2016 as a result of any slot reductions received services described in §§ 1302.70 and 1302.72 to facilitate successful transitions to other programs.

PART 1303—FINANCIAL AND ADMINISTRATIVE REQUIREMENTS

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Authority: 42 U.S.C. 9801 *et seq.*

§ 1303.1 Overview.

Section 641A of the Act requires that the Secretary modify as necessary program performance standards including administrative and financial management standards (section 641A(a)(1)(C)). This part specifies the financial and administrative requirements of agencies. Subpart A of this part outlines the financial requirements consistent with sections 640(b) and 644(b) and (c) of the Act. Subpart B of this part specifies the administrative requirements consistent with sections 644(a)(1), 644(e), 653, 654, 655, 656, and 657A of the Act. Subpart C of this part implements the statutory provision at section 641A(b)(4) of the Act that directs the Secretary to ensure the confidentiality of any personally identifiable data, information, and records collected or maintained. Subpart D of this part prescribes regulations for the operation of delegate agencies consistent with Section 641(A)(d). Subpart E of this part implements the statutory requirements in Section 644(c), (f) and (g) related to facilities. Subpart F prescribes regulations on transportation consistent with section 640(i) of the Act.

Subpart A—Financial Requirements

§ 1303.2 Purpose.

This subpart establishes regulations applicable to program administration and grants management for all grants under the Act.

§ 1303.3 Other requirements.

The following chart includes HHS regulations that apply to all grants made under the Act:

Cite	Title
45 CFR part 16	Department grant appeals process.
45 CFR part 30	HHS Standards and Procedures for Claims collection.
45 CFR part 46	Protection of human subjects.
45 CFR part 75	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
45 CFR part 80	Nondiscrimination under programs receiving federal assistance through the Department of Health and Human Services—Effectuation of title VI and VII of the Civil Rights Act of 1964.
45 CFR part 81	Practice and procedure for hearings under part 80.
45 CFR part 84	Nondiscrimination on the basis of handicap in federally assisted programs.
45 CFR part 87	Equal treatment for faith based organizations.
2 CFR part 170	FFATA Sub-award and executive compensation.
2 CFR 25.110	CCR/DUNS requirement.

§ 1303.4 Federal financial assistance, non-federal match, and waiver requirements.

In accordance with section 640(b) of the Act, federal financial assistance to a grantee will not exceed 80 percent of the approved total program costs. A grantee must contribute 20 percent as non-federal match each budget period. The responsible HHS official may approve a waiver of all or a portion of the non-federal match requirement on the basis of the grantee's written application submitted for the budget period and any supporting evidence the responsible HHS official requires. In deciding whether to grant a waiver, the responsible HHS official will consider the circumstances specified at section 640(b) of the Act and whether the grantee has made a reasonable effort to comply with the non-federal match requirement.

§ 1303.5 Limitations on development and administrative costs.

(a) *Limitations.* (1) Costs to develop and administer a program cannot be excessive or exceed 15 percent of the total approved program costs. Allowable costs to develop and administer a Head Start program cannot exceed 15 percent of the total approved program costs, which includes both federal costs and non-federal match, unless the responsible HHS official grants a waiver under paragraph (b) of this section that approves a higher percentage in order to carry out the purposes of the Act.

(2) To assess total program costs and determine whether a grantee meets this requirement, the grantee must:

(i) Determine the costs to develop and administer its program, including the local costs of necessary resources;

(ii) Categorize total costs as development and administrative or program costs;

(iii) Identify and allocate the portion of dual benefits costs that are for development and administration;

(iv) Identify and allocate the portion of indirect costs that are for development and administration versus program costs; and,

(v) Delineate all development and administrative costs in the grant application and calculate the percentage of total approved costs allocated to development and administration.

(b) *Waivers.* (1) The responsible HHS official may grant a waiver for each budget period if a delay or disruption to program services is caused by circumstances beyond the agency's control, or if an agency is unable to administer the program within the 15 percent limitation and if the agency can demonstrate efforts to reduce its development and administrative costs.

(2) If at any time within the grant funding cycle, a grantee estimates development and administration costs will exceed 15 percent of total approved costs, it must submit a waiver request to the responsible HHS official that explains why costs exceed the limit, that indicates the time period the waiver will cover, and that describes what the grantee will do to reduce its development and administrative costs to comply with the 15 percent limit after the waiver period.

Subpart B—Administrative Requirements

§ 1303.10 Purpose.

A grantee must observe standards of organization, management, and administration that will ensure, so far as reasonably possible, that all program activities are conducted in a manner consistent with the purposes of the Act and the objective of providing assistance effectively, efficiently, and free of any taint of partisan political bias or personal or family favoritism.

§ 1303.11 Limitations and prohibitions.

An agency must adhere to sections 644(e), 644(g)(3), 653, 654, 655, 656, and 657A of the Act. These sections pertain to union organizing, the Davis-Bacon Act, limitations on compensation, nondiscrimination, unlawful activities, political activities, and obtaining parental consent.

§ 1303.12 Insurance and bonding.

An agency must have an ongoing process to identify risks and have cost-effective insurance for those identified risks; a grantee must require the same for its delegates. The agency must specifically consider the risk of accidental injury to children while participating in the program. The grantee must submit proof of appropriate coverage in its initial application for funding. The process of identifying risks must also consider the risk of losses resulting from fraudulent acts by individuals authorized to disburse Head Start funds. Consistent with 45 CFR part 75, if the agency lacks sufficient coverage to protect the federal government's interest, the agency must maintain adequate fidelity bond coverage.

Subpart C—Protections for the Privacy of Child Records

§ 1303.20 Establishing procedures.

A program must establish procedures to protect the confidentiality of any personally identifiable information (PII) in child records.

§ 1303.21 Program procedures—applicable confidentiality provisions.

(a) If a program is an educational agency or institution that receives funds under a program administered by the Department of Education and therefore is subject to the confidentiality provisions under the Family Educational Rights and Privacy Act (FERPA), then it must comply with those confidentiality provisions of FERPA instead of the provisions in this subpart.

(b) If a program serves a child who is referred to, or found eligible for services under, IDEA, then a program must comply with the applicable confidentiality provisions in Part B or Part C of IDEA to protect the PII in records of those children, and, therefore, the provisions in this subpart do not apply to those children.

§ 1303.22 Disclosures with, and without, parental consent.

(a) *Disclosure with parental consent.* (1) Subject to the exceptions in paragraphs (b) and (c) of this section, the procedures to protect PII must require the program to obtain a parent's written consent before the program may disclose such PII from child records.

(2) The procedures to protect PII must require the program to ensure the parent's written consent specifies what child records may be disclosed, explains why the records will be disclosed, and identifies the party or class of parties to whom the records may be disclosed. The written consent must be signed and dated.

(3) "Signed and dated written consent" under this part may include a record and signature in electronic form that:

(i) Identifies and authenticates a particular person as the source of the electronic consent; and,

(ii) Indicates such person's approval of the information.

(4) The program must explain to the parent that the granting of consent is voluntary on the part of the parent and may be revoked at any time. If a parent revokes consent, that revocation is not retroactive and therefore it does not apply to an action that occurred before the consent was revoked.

(b) *Disclosure without parental consent but with parental notice and opportunity to refuse.* The procedures to protect PII must allow the program to disclose such PII from child records without parental consent if the program notifies the parent about the disclosure, provides the parent, upon the parent's request, a copy of the PII from child records to be disclosed in advance, and gives the parent an opportunity to challenge and refuse disclosure of the information in the records, before the program forwards the records to officials at a program, school, or school district in which the child seeks or intends to enroll or where the child is already enrolled so long as the disclosure is related to the child's enrollment or transfer.

(c) *Disclosure without parental consent.* The procedures to protect PII must allow the program to disclose such PII from child records without parental consent to:

(1) Officials within the program or acting for the program, such as contractors and subrecipients, if the official provides services for which the program would otherwise use employees, the program determines it is necessary for Head Start services, and the program maintains oversight with respect to the use, further disclosure, and maintenance of child records, such as through a written agreement;

(2) Officials within the program, acting for the program, or from a federal or state entity, in connection with an audit or evaluation of education or child development programs, or for enforcement of or compliance with federal legal requirements of the program; provided the program maintains oversight with respect to the use, further disclosure, and maintenance of child records, such as through a written agreement, including the destruction of the PII when no longer needed for the purpose of the disclosure, except when the disclosure is specifically authorized by federal law or by the responsible HHS official;

(3) Officials within the program, acting for the program, or from a federal or state entity, to conduct a study to improve child and family outcomes, including improving the quality of programs, for, or on behalf of, the program, provided the program maintains oversight with respect to the use, further disclosure, and maintenance of child records, such as through a written agreement, including the destruction of the PII when no longer needed for the purpose of the disclosure;

(4) Appropriate parties in order to address a disaster, health or safety emergency during the period of the emergency, or a serious health and safety risk such as a serious food allergy, if the program determines that disclosing the PII from child records is necessary to protect the health or safety of children or other persons;

(5) Comply with a judicial order or lawfully issued subpoena, provided the program makes a reasonable effort to notify the parent about all such subpoenas and court orders in advance of the compliance therewith, unless:

(i) A court has ordered that neither the subpoena, its contents, nor the information provided in response be disclosed;

(ii) The disclosure is in compliance with an ex parte court order obtained by the United States Attorney General (or designee not lower than an Assistant Attorney General) concerning investigations or prosecutions of an offense listed in 18 U.S.C. 2332b(g)(5)(B) or an act of domestic or international terrorism as defined in 18 U.S.C. 2331.

(iii) A parent is a party to a court proceeding directly involving child abuse and neglect (as defined in section 3 of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101)) or dependency matters, and the order is issued in the context of that proceeding, additional notice to the parent by the program is not required; or,

(iv) A program initiates legal action against a parent or a parent initiates legal action against a program, then a program may disclose to the court, also without a court order or subpoena, the child records relevant for the program to act as plaintiff or defendant.

(6) The Secretary of Agriculture or an authorized representative from the Food and Nutrition Service to conduct program monitoring, evaluations, and performance measurements for the Child and Adult Care Food Program under the Richard B. Russell National School Lunch Act or the Child Nutrition Act of 1966, if the results will be reported in an aggregate form that does not identify any individual: Provided, that any data collected must be protected in a manner that will not permit the personal identification of students and their parents by other than the authorized representatives of the Secretary of Agriculture and any PII must be destroyed when the data are no longer needed for program monitoring, evaluations, and performance measurements;

(7) A caseworker or other representative from a state, local, or tribal child welfare agency, who has the right to access a case plan for a child who is in foster care placement, when such agency is legally responsible for the child's care and protection, under state or tribal law, if the agency agrees in writing to protect PII, to use information from the child's case plan for specific purposes intended of addressing the child's needs, and to

destroy information that is no longer needed for those purposes; and,

(8) Appropriate parties in order to address suspected or known child maltreatment and is consistent with applicable federal, state, local, and tribal laws on reporting child abuse and neglect.

(d) *Written agreements.* When a program establishes a written agreement with a third party, the procedures to protect such PII must require the program to annually review and, if necessary, update the agreement. If the third party violates the agreement, then the program may:

(1) Provide the third party an opportunity to self-correct; or,

(2) Prohibit the third party from access to records for a set period of time as established by the programs governing body and policy council.

(e) *Annual notice.* The procedures to protect PII must require the program to annually notify parents of their rights in writing described in this subpart and applicable definitions in part 1305 of this chapter, and include in that notice a description of the types of PII that may be disclosed, to whom the PII may be disclosed, and what may constitute a necessary reason for the disclosure without parental consent as described in paragraph (c) of this section.

(f) *Limit on disclosing PII.* A program must only disclose the information that is deemed necessary for the purpose of the disclosure.

§ 1303.23 Parental rights.

(a) *Inspect record.* (1) A parent has the right to inspect child records.

(2) If the parent requests to inspect child records, the program must make the child records available within a reasonable time, but no more than 45 days after receipt of request.

(3) If a program maintains child records that contain information on more than one child, the program must ensure the parent only inspects information that pertains to the parent's child.

(4) The program shall not destroy a child record with an outstanding request to inspect and review the record under this section.

(b) *Amend record.* (1) A parent has the right to ask the program to amend information in the child record that the parent believes is inaccurate, misleading, or violates the child's privacy.

(2) The program must consider the parent's request and, if the request is denied, render a written decision to the parent within a reasonable time that informs the parent of the right to a hearing.

(c) *Hearing.* (1) If the parent requests a hearing to challenge information in the child record, the program must schedule a hearing within a reasonable time, notify the parent, in advance, about the hearing, and ensure the person who conducts the hearing does not have a direct interest in its outcome.

(2) The program must ensure the hearing affords the parent a full and fair opportunity to present evidence relevant to the issues.

(3) If the program determines from evidence presented at the hearing that the information in the child records is inaccurate, misleading, or violates the child's privacy, the program must either amend or remove the information and notify the parent in writing.

(4) If the program determines from evidence presented at the hearing that information in the child records is accurate, does not mislead, or otherwise does not violate the child's privacy, the program must inform the parent of the right to place a statement in the child records that either comments on the contested information or that states why the parent disagrees with the program's decision, or both.

(d) *Right to copy of record.* The program must provide a parent, free of charge, an initial copy of child records disclosed to third parties with parental consent and, upon parent request, an initial copy of child records disclosed to third parties, unless the disclosure was for a court that ordered neither the subpoena, its contents, nor the information furnished in response be disclosed.

(e) *Right to inspect written agreements.* A parent has the right to review any written agreements with third parties.

§ 1303.24 Maintaining records.

(a) A program must maintain child records in a manner that ensures only parents, and officials within the program or acting on behalf of the program have access, and such records must be destroyed within a reasonable timeframe after such records are no longer needed or required to be maintained.

(b) A program must maintain, with the child records, for as long as the records are maintained, information on all individuals, agencies, or organizations to whom a disclosure of PII from the child records was made (except for program officials and parents) and why the disclosure was made. If a program uses a web-based data system to maintain child records, the program must ensure such child records are adequately protected and maintained according to current industry security standards.

(c) If a parent places a statement in the child record, the program must maintain the statement with the contested part of the child record for as long as the program maintains the record and, disclose the statement whenever it discloses the portion of the child record to which the statement relates.

Subpart D—Delegation of Program Operations

§ 1303.30 Grantee responsibility and accountability.

A grantee is accountable for the services its delegate agencies provide. The grantee supports, oversees and ensures delegate agencies provide high-quality services to children and families and meet all applicable Head Start requirements. The grantee can only terminate a delegate agency if the grantee shows cause why termination is necessary and provides a process for delegate agencies to appeal termination decisions. The grantee retains legal responsibility and authority and bears financial accountability for the program when services are provided by delegate agencies.

§ 1303.31 Determining and establishing delegate agencies.

(a) If a grantee enters into an agreement with another entity to serve children, the grantee must determine whether the agreement meets the definition of "delegate agency" in section 637(3) of the Act.

(b) A grantee must not award a delegate agency federal financial assistance unless there is a written agreement and the responsible HHS official approves the agreement before the grantee delegates program operations.

§ 1303.32 Evaluations and corrective actions for delegate agencies.

A grantee must evaluate and ensure corrective action for delegate agencies according to section 641A(d) of the Act.

§ 1303.33 Termination of delegate agencies.

(a) If a grantee shows cause why termination is appropriate or demonstrates cost effectiveness, the grantee may terminate a delegate agency's contract.

(b) The grantee's decision to terminate must not be arbitrary or capricious.

(c) The grantee must establish a process for defunding a delegate agency, including an appeal of a defunding decision and must ensure the process is fair and timely.

(d) The grantee must notify the responsible HHS official about the appeal and its decision.

Subpart E—Facilities

§ 1303.40 Purpose.

This subpart prescribes what a grantee must establish to show it is eligible to purchase, construct and renovate facilities as outlined in section 644(c), (f) and (g) of the Act. It explains how a grantee may apply for funds, details what measures a grantee must take to protect federal interest in facilities purchased, constructed or renovated with grant funds, and concludes with other administrative provisions. This subpart applies to major renovations. It only applies to minor renovations and repairs, when they are included with a purchase application and are part of purchase costs.

§ 1303.41 Approval of previously purchased facilities.

If a grantee purchased a facility after December 31, 1986, and seeks to use grant funds to continue to pay purchase costs for the facility or to refinance current indebtedness and use grant funds to service the resulting debt, the grantee may apply for funds to meet those costs. The grantee must submit an application that conforms to requirements in this part and in the Act to the responsible HHS official. If the responsible HHS official approves the grantee's application, Head Start funds may be used to pay ongoing purchase costs, which include principal and interest on approved loans.

§ 1303.42 Eligibility to purchase, construct, and renovate facilities.

(a) *Preliminary eligibility.* (1) Before a grantee can apply for funds to purchase, construct, or renovate a facility under § 1303.44, it must establish that:

(i) The facility will be available to Indian tribes, or rural or other low-income communities;

(ii) The proposed purchase, construction or major renovation is within the grantee's designated service area; and,

(iii) The proposed purchase, construction or major renovation is necessary because the lack of suitable facilities in the grantee's service area will inhibit the operation of the program.

(2) If a program applies to construct a facility, that the construction of such facility is more cost-effective than the purchase of available facilities or renovation.

(b) *Proving a lack of suitable facilities.* To satisfy paragraph (a)(1)(iii) of this section, the grantee must have a written statement from an independent real estate professional familiar with the commercial real estate market in the grantee's service area, that includes factors considered and supports how the real estate professional determined there are no other suitable facilities in the area.

§ 1303.43 Use of grant funds to pay fees.

A grantee may submit a written request to the responsible HHS official for reasonable fees and costs necessary to determine preliminary eligibility under § 1303.42 before it submits an application under § 1303.44. If the responsible HHS official approves the grantee's application, the grantee may use federal funds to pay fees and costs.

§ 1303.44 Applications to purchase, construct, and renovate facilities.

(a) *Application requirements.* If a grantee is preliminarily eligible under § 1303.42 to apply for funds to purchase, construct, or renovate a facility, it must submit to the responsible HHS official:

(1) A statement that explains the anticipated effect the proposed purchase, construction or renovation has had or will have on program enrollment, activities and services, and how it determined what the anticipated effect would be;

(2) A deed or other document showing legal ownership of the real property where facilities activity is proposed, legal description of the facility site, and an explanation why the location is appropriate for the grantee's service area;

(3) Plans and specifications for the facility, including square footage, structure type, the number of rooms the facility will have or has, how the rooms will be used, where the structure will be positioned or located on the building site, and whether there is space available for outdoor play and for parking;

(4) Certification by a licensed engineer or architect that the facility is, or will be upon completion, structurally sound and safe for use as a Head Start facility and that the facility complies, or will comply upon completion, with local building codes, applicable child care licensing requirements, the accessibility requirements of the Americans with Disabilities Act, section 504 of the Rehabilitation Act of 1973, the Flood Disaster Protection Act of 1973, and the National Historic Preservation Act of 1966;

(5) A description of proposed renovations or repairs to make the facility suitable for program activities, and plans and specification that describe the facility after renovation or repair;

(6) A proposed schedule that details when the grantee will acquire, renovate, repair and occupy the facility;

(7) An estimate by a licensed independent certified appraiser of the facility's fair market value after proposed purchase and associated repairs and renovations construction, or major renovation is completed is required for all facilities activities except for major renovations to leased property;

(8) The cost comparison described in § 1303.45;

(9) A statement that shows what share of the purchase, construction, or major renovation will be paid with grant funds and what the grantee proposes to contribute as a nonfederal match to the purchase, construction or major renovation;

(10) A statement from a lender, if a grantee applies to use Head Start funds to continue purchase on a facility or refinance existing debt on a facility that indicates the lender is willing to comply with § 1303.49;

(11) The terms of any proposed or existing loan(s) related to purchase, construction or major renovation of the facility, including copies of any funding commitment letters, mortgages, promissory notes, potential security agreements to be entered into, information on all other sources of funding, construction or major renovation, and any restrictions or conditions imposed by other funding sources;

(12) A Phase I environmental site assessment that describes the environmental condition of the proposed facility site and any structures on the site;

(13) A description of the efforts by the grantee to coordinate or collaborate with other providers in the community to seek assistance, including financial assistance, prior to the use of funds under this section; and,

(14) Any additional information the responsible HHS official may require.

(b) *Additional requirements for leased properties.* (1) If a grantee applies to renovate leased property, it must submit to the responsible HHS official information described in paragraph (a) of this section, a copy of the existing or proposed lease agreement, and the landlord or lessor's consent.

(2) If a grantee applies to purchase a modular unit it intends to site on leased property or on other property the grantee does not own, the grantee must submit to the responsible HHS official information described in paragraph (a) of this section and a copy of the

proposed lease or other occupancy agreement that will allow the grantee access to the modular unit for at least 15 years.

(c) *Non-federal match.* Any non-federal match associated with facilities activities becomes part of the federal share of the facility.

§ 1303.45 Cost-comparison to purchase, construct, and renovate facilities.

(a) *Cost comparison.* (1) If a grantee proposes to purchase, construct, or renovate a facility, it must submit a detailed cost estimate of the proposed activity, compare the costs associated with the proposed activity to other available alternatives in the service area, and provide any additional information the responsible HHS official requests. The grantee must demonstrate that the proposed activity will result in savings when compared to the costs that would be incurred to acquire the use of an alternative facility to carry out program.

(2) In addition to requirements in paragraph (a)(1) of this section, the grantee must:

(i) Identify who owns the property;

(ii) List all costs related to the purchase, construction, or renovation;

(iii) Identify costs over the structure's useful life, which is at least 20 years for a facility that the grantee purchased or constructed and at least 15 years for a modular unit the grantee renovated, and deferred costs, including mortgage balloon payments, as costs with associated due dates; and,

(iv) Demonstrate how the proposed purchase, construction, or major renovation is consistent with program management and fiscal goals, community needs, enrollment and program options and how the proposed facility will support the grantee as it provides quality services to children and families.

(b) *Continue purchase or refinance.* To use funds to continue purchase on a facility or to refinance an existing indebtedness, the grantee must compare the costs of continued purchase against the cost of purchasing a comparable facility in the service area over the remaining years of the facility's useful life. The grantee must demonstrate that the proposed activity will result in savings when compared to the cost that would be incurred to acquire the use of an alternative facility to carry out the program.

(c) *Multi-purpose use.* If the grantee intends to use a facility to operate a Head Start program and for another purpose, it must disclose what percentage of the facility will be used for non-Head Start activities, along with costs associated with those activities, in accordance with applicable cost principles.

§ 1303.46 Recording and posting notices of federal interest.

(a) *Survival of federal interest.* A grantee that receives funds under this subpart must file notices of federal interest as set forth in paragraph (b) of this section. Federal interest cannot be defeated by a grantee's failure to file a notice of federal interest.

(b) *Recording notices of federal interest.* (1) If a grantee uses federal funds to purchase real property or a facility, excluding modular units, appurtenant to real property, it must record a notice of federal interest in the official real property records for the jurisdiction where the facility is or will be located. The grantee must file the notice of federal interest as soon as it uses Head Start funds to either fully or partially purchase a facility or real property where a facility will be constructed or as soon as it receives permission from the responsible HHS official to use Head Start funds to continue purchase on a facility.

(2) If a grantee uses federal funds in whole or in part to construct a facility, it must record the notice of federal interest in the official real property records for the jurisdiction in which the facility is located as soon as it receives the notice of award to construct the facility.

(3) If a grantee uses federal funds to renovate a facility that it, or a third party owns, the grantee must record the notice of federal interest in the official real property records for the jurisdiction in which the facility is located as soon as it receives the notice of award to renovate the facility.

(4) If a grantee uses federal funds in whole or in part to purchase a modular unit or to renovate a modular unit, the grantee must post the notice of federal interest, in clearly visible locations, on the exterior of the modular unit and inside the modular unit.

§ 1303.47 Contents of notices of federal interest.

(a) *Facility and real property a grantee owns.* A notice of federal interest for a facility, other than a modular unit, and real property the grantee owns or will own, must include:

(1) The grantee's correct legal name and current mailing address;

(2) A legal description of the real property;

(3) Grant award number, amount and date of initial facilities funding award or initial use of base grant funds for ongoing purchase or mortgage payments;

(4) A statement that the notice of federal interest includes funds awarded in grant award(s) and any Head Start funds subsequently used to purchase, construct or to make major renovations to the real property;

(5) A statement that the facility and real property will only be used for purposes consistent with the Act and applicable Head Start regulations;

(6) A statement that the facility and real property will not be mortgaged or used as collateral, sold or otherwise transferred to another party, without the responsible HHS official's written permission;

(7) A statement that the federal interest cannot be subordinated, diminished, nullified or released through encumbrance of the property, transfer of the property to another party or any other action the grantee takes without the responsible HHS official's written permission;

(8) A statement that confirms that the agency's governing body received a copy of the notice of federal interest prior to filing and the date the governing body was provided with a copy; and,

(9) The name, title, and signature of the person who drafted the notice.

(b) *Facility leased by a grantee.* (1) A notice of federal interest for a leased facility, excluding a modular unit, on land the grantee does not own, must be recorded in the official real property records for the jurisdiction where the facility is located and must include:

(i) The grantee's correct legal name and current mailing address;

(ii) A legal description of affected real property;

(iii) The grant award number, amount and date of initial funding award or initial use of base grant funds for major renovation;

(iv) Acknowledgement that the notice of federal interest includes any Head Start funds subsequently used to make major renovations on the affected real property;

(v) A statement the facility and real property will only be used for purposes consistent with the Act and applicable Head Start regulations; and,

(vi) A lease or occupancy agreement that includes the required information from paragraphs (b)(1)(i) through (v) of this section may be recorded in the official real property records for the jurisdiction where the facility is located to serve as a notice of federal interest.

(2) If a grantee cannot file the lease or occupancy agreement described in paragraph (b)(1)(vi) of this section in the official real property records for the jurisdiction where the facility is located, it may file an abstract. The abstract must include the names and addresses of

parties to the lease or occupancy agreement, terms of the lease or occupancy agreement, and information described in paragraphs (a)(1) through (9) of this section.

(c) *Modular units.* A notice of federal interest on a modular unit the grantee purchased or renovated must be visible and clearly posted on the exterior of the modular and inside the modular and must include:

(1) The grantee's correct legal name and current mailing address;

(2) The grant award number, amount and date of initial funding award or initial use of base grant funds to purchase or renovate;

(3) A statement that the notice of federal interest includes any Head Start funds subsequently used for major renovations to the modular unit;

(4) A statement that the facility and real property will only be used for purposes consistent with the Act and applicable Head Start regulations;

(5) A statement that the modular unit will not be mortgaged or used as collateral, sold or otherwise transferred to another party, without the responsible HHS official's written permission;

(6) A statement that the federal interest cannot be subordinated, diminished, nullified or released through encumbrance of the property, transfer to another party, or any other action the grantee takes without the responsible HHS official's written permission;

(7) A statement that the modular unit cannot be moved to another location without the responsible HHS official's written permission;

(8) A statement that confirms that the agency's governing body has received a copy of the filed notice of federal interest and the date the governing body was provided with a copy; and,

(9) The name, title, and signature of the person who completed the notice for the grantee agency.

§ 1303.48 Grantee limitations on federal interest.

(a) A grantee cannot mortgage, use as collateral for a credit line or for other loan obligations, or, sell or transfer to another party, a facility, real property, or a modular unit it has purchased, constructed or renovated with Head Start funds, without the responsible HHS official's written permission.

(b) A grantee must have the responsible HHS official's written permission before it can use real property, a facility, or a modular unit subject to federal interest for a purpose other than that for which the grantee's application was approved.

§ 1303.49 Protection of federal interest in mortgage agreements.

(a) Any mortgage agreement or other security instrument that is secured by real property or a modular unit constructed or purchased in whole or in part with federal funds or subject to renovation with federal funds must:

(1) Specify that the responsible HHS official can intervene in case the grantee defaults on, terminates or withdraws from the agreement;

(2) Designate the responsible HHS official to receive a copy of any notice of default given to the grantee under the terms of the agreement and include the regional grants management officer's current address;

(3) Include a clause that requires any action to foreclose the mortgage agreement or security agreement be suspended for 60 days after the responsible HHS official receives the default notice to allow the responsible HHS official reasonable time to respond;

(4) Include a clause that preserves the notice of federal interest and the grantee's obligation for its federal share if the responsible HHS official fails to respond to any notice of default provided under this section;

(5) Include a statement that requires the responsible HHS official to be paid the federal interest before foreclosure proceeds are paid to the lender, unless the official's rights under the notice of federal interest have been subordinated by a written agreement in conformance with § 1303.51;

(6) Include a clause that gives the responsible HHS official the right to cure any default under the agreement within the designated period to cure the default; and,

(7) Include a clause that gives the responsible HHS official the right to assign or transfer the agreement to another interim or permanent grantee.

(b) A grantee must immediately notify the responsible HHS official of any default under an agreement described in paragraph (a) of this section.

§ 1303.50 Third party leases and occupancy arrangements.

(a) After November 7, 2016, if a grantee receives federal funds to purchase, construct or renovate a facility on real property the grantee does not own or to purchase or renovate a modular unit on real property the grantee does not own, the grantee must have a lease or other occupancy agreement of at least 30 years for purchase or construction of a facility and at least 15 years for a major renovation or placement of a modular unit.

(b) The lease or occupancy agreement must:

(1) Provide for the grantee's right of continued use and occupancy of the leased or occupied premises during the entire term of the lease;

(2) Designate the regional grants management officer to receive a copy of any notice of default given to the grantee under the terms of the agreement and include the regional grants management officer's current address;

(3) Specify that the responsible HHS official has the right to cure any default under the lease or occupancy agreement within the designated period to cure default; and,

(4) Specify that the responsible HHS official has the right to transfer the lease to another interim or replacement grantee.

§ 1303.51 Subordination of the federal interest.

Only the responsible HHS official can subordinate federal interest to the rights of a lender or other third party. Subordination agreements must be in writing and the mortgage agreement or security agreement for which subordination is requested must comply with § 1303.49. When the amount of federal funds already contributed to the facility exceeds the amount to be provided by the lender seeking subordination, the federal interest may only be subordinated if the grantee can show that funding is not available without subordination of the federal interest.

§ 1303.52 Insurance, bonding, and maintenance.

(a) *Purpose.* If a grantee uses federal funds to purchase or continue purchase on a facility, excluding modular units, the grantee must obtain a title insurance policy for the purchase price that names the responsible HHS official as an additional loss payee.

(b) *Insurance coverage.* (1) If a grantee uses federal funds to purchase or continue purchase on a facility or modular unit the grantee must maintain physical damage or destruction insurance at the full replacement value of the facility, for as long as the grantee owns or occupies the facility.

(2) If a facility is located in an area the National Flood Insurance Program defines as high risk, the grantee must maintain flood insurance for as long as the grantee owns or occupies the facility.

(3) A grantee must submit to the responsible HHS official, within 10 days after coverage begins, proof of insurance coverage required under paragraphs (a) and (b) of this section.

(c) *Maintenance.* A grantee must keep all facilities purchased or constructed in whole or in part with Head Start funds in good repair in accordance with all applicable federal, state, and local laws, rules and regulations, including Head Start requirements, zoning requirements, building codes, health and safety regulations and child care licensing standards.

§ 1303.53 Copies of documents.

A grantee must submit to the responsible HHS official, within 10 days after filing or execution, copies of deeds, leases, loan instruments, mortgage agreements, notices of federal interest, and other legal documents related to the use of Head Start funds for purchase, construction, major renovation, or the discharge of any debt secured by the facility.

§ 1303.54 Record retention.

A grantee must retain records pertinent to the lease, purchase, construction or renovation of a facility funded in whole or in part with Head Start funds, for as long as the grantee owns or occupies the facility, plus three years.

§ 1303.55 Procurement procedures.

(a) A grantee must comply with all grants management regulations, including specific regulations applicable to transactions in excess of the current simplified acquisition threshold, cost principles, and its own procurement procedures, and must provide, to the maximum extent practical, open and full competition.

(b) A grantee must obtain the responsible HHS official's written approval before it uses Head Start funds, in whole or in part, to contract construction or renovation services. The grantee must ensure these contracts are paid on a lump sum fixed-price basis.

(c) A grantee must obtain prior written approval from the responsible HHS official for contract modifications that would change the scope or objective of a project or would materially alter the costs, by increasing the amount of grant funds needed to complete the project.

(d) A grantee must ensure all construction and renovation contracts paid, in whole or in part with Head Start funds contain a clause that gives the responsible HHS official or his or her designee access to the facility, at all reasonable times, during construction and inspection.

§ 1303.56 Inspection of work.

The grantee must submit to the responsible HHS official a final facility inspection report by a licensed engineer or architect within 30 calendar days after the project is completed. The inspection report must certify that the facility complies with local building codes, applicable child care licensing requirements, is structurally sound and safe for use as a Head Start facility, complies with the access requirements of the Americans with Disabilities Act, section 504 of the Rehabilitation Act, and the Flood Disaster Protection Act of 1973, and complies with National Historic Preservation Act of 1966.

Subpart F—Transportation

§ 1303.70 Purpose.

(a) *Applicability.* This rule applies to all agencies, including those that provide transportation services, with the exceptions and exclusions provided in this section, regardless of whether such transportation is provided directly on agency owned or leased vehicles or through arrangement with a private or public transportation provider.

(b) *Providing transportation services.* (1) If a program does not provide transportation services, either for all or a portion of the children, it must provide reasonable assistance, such as information about public transit availability, to the families of such children to arrange transportation to and from its activities, and provide information about these transportation options in recruitment announcements.

(2) A program that provides transportation services must make reasonable efforts to coordinate transportation resources with other human services agencies in its community in order to control costs and to improve the quality and the availability of transportation services.

(3) A program that provides transportation services must ensure all accidents involving vehicles that transport children are reported in accordance with applicable state requirements.

(c) *Waiver.* (1) A program that provides transportation services must comply with all provisions in this subpart. A Head Start program may request to waive a specific requirement in this part, in writing, to the responsible HHS official, as part of an agency's annual application for financial assistance or amendment and must submit any required documentation the responsible HHS official deems necessary to support the waiver. The responsible HHS official is not authorized to waive any requirements with regard to children enrolled in an Early Head Start program. A program may request a waiver when:

(i) Adherence to a requirement in this part would create a safety hazard in the circumstances faced by the agency; and,

(ii) For preschool children, compliance with requirements related to child restraint systems at §§ 1303.71(d) and 1303.72(a)(1) or bus monitors at § 1303.72(a)(4) will result in a significant disruption to the program and the agency demonstrates that waiving such requirements is in the best interest of the children involved.

(2) The responsible HHS official is not authorized to waive any requirements of the Federal Motor Vehicle Safety Standards (FMVSS) made applicable to any class of vehicle under 49 CFR part 571.

§ 1303.71 Vehicles.

(a) *Required use of schools buses or allowable alternative vehicles.* A program, with the exception of transportation services to children served under a home-based option, must ensure all vehicles used or purchased with grant funds to provide transportation services to enrolled children are school buses or allowable alternate vehicles that are equipped for use of height- and weight-appropriate child restraint systems, and that have reverse beepers.

(b) *Emergency equipment.* A program must ensure each vehicle used in providing such services is equipped with an emergency communication system clearly labeled and appropriate emergency safety equipment, including a seat belt cutter, charged fire extinguisher, and first aid kit.

(c) *Auxiliary seating.* A program must ensure any auxiliary seating, such as temporary or folding jump seats, used in vehicles of any type providing such services are built into the vehicle by the manufacturer as part of its standard design, are maintained in proper working order, and are inspected as part of the annual inspection required under paragraph (e)(2)(i) of this section.

(d) *Child restraint systems.* A program must ensure each vehicle used to transport children receiving such services is equipped for use of age-, height- and weight-appropriate child safety restraint systems as defined in part 1305 of this chapter.

(e) *Vehicle maintenance.* (1) A program must ensure vehicles used to provide such services are in safe operating condition at all times.

(2) The program must:

(i) At a minimum, conduct an annual thorough safety inspection of each vehicle through an inspection program licensed or operated by the state;

(ii) Carry out systematic preventive maintenance on vehicles; and,

(iii) Ensure each driver implements daily pre-trip vehicle inspections.

(f) *New vehicle inspection.* A program must ensure bid announcements for school buses and allowable alternate vehicles to transport children in its program include correct specifications and a clear statement of the vehicle's intended use. The program must ensure vehicles are examined at delivery to ensure they are equipped in accordance with the bid specifications and that the manufacturer's certification of compliance with the applicable FMVSS is included with the vehicle.

§ 1303.72 Vehicle operation.

(a) *Safety.* A program must ensure:

(1) Each child is seated in a child restraint system appropriate to the child's age, height, and weight;

(2) Baggage and other items transported in the passenger compartment are properly stored and secured, and the aisles remain clear and the doors and emergency exits remain unobstructed at all times;

(3) Up-to-date child rosters and lists of the adults each child is authorized to be released to, including alternates in case of emergency, are maintained and no child is left behind, either at the classroom or on the vehicle at the end of the route; and,

(4) With the exception of transportation services to children served under a home-based option, there is at least one bus monitor on board at all times, with additional bus monitors provided as necessary.

(b) *Driver qualifications.* A program, with the exception of transportation services to children served under a home-based option, must ensure drivers, at a minimum:

(1) In states where such licenses are granted, have a valid Commercial Driver's License (CDL) for vehicles in the same class as the vehicle the driver will operating; and,

(2) Meet any physical, mental, and other requirements as necessary to perform job-related functions with any necessary reasonable accommodations.

(c) *Driver application review.* In addition to the applicant review process prescribed § 1302.90(b) of this chapter, a program, with the exception of transportation services to children served under a home-based option, must ensure the applicant review process for drivers includes, at minimum:

(1) Disclosure by the applicant of all moving traffic violations, regardless of penalty;

(2) A check of the applicant's driving record through the appropriate state agency, including a check of the applicant's record through the National Driver Register, if available;

(3) A check that drivers qualify under the applicable driver training requirements in the state or tribal jurisdiction; and,

(4) After a conditional employment offer to the applicant and before the applicant begins work as a driver, a medical examination, performed by a licensed doctor of medicine or osteopathy, establishing that the individual possesses the physical ability to perform any job-related functions with any necessary accommodations.

(d) *Driver training.* (1) A program must ensure any person employed as a driver receives training prior to transporting any enrolled child and receives refresher training each year.

(2) Training must include:

(i) Classroom instruction and behind-the-wheel instruction sufficient to enable the driver to operate the vehicle in a safe and efficient manner, to safely run a fixed route, to administer basic first aid in case of injury, and to handle emergency situations, including vehicle evacuation, operate any special equipment, such as wheelchair lifts, assistance devices or special occupant restraints, conduct routine maintenance and safety checks of the vehicle, and maintain accurate records as necessary; and,

(ii) Instruction on the topics listed in § 1303.75 related to transportation services for children with disabilities.

(3) A program must ensure the annual evaluation of each driver of a vehicle used to provide such services includes an on-board observation of road performance.

(e) *Bus monitor training.* A program must train each bus monitor before the monitor begins work, on child boarding and exiting procedures, how to use child restraint systems, completing any required paperwork, how to respond to emergencies and emergency evacuation procedures, how to use special equipment, child pick-up and release procedures, how to conduct and pre- and post-trip vehicle checks. Bus monitors are also subject to staff safety training requirements in § 1302.47(b)(4) of this chapter including Cardio Pulmonary Resuscitation (CPR) and first aid.

§ 1303.73 Trip routing.

(a) A program must consider safety of the children it transports when it plans fixed routes.

(b) A program must also ensure:

(1) The time a child is in transit to and from the program must not exceed one hour unless there is no shorter route available or any alternative shorter route is either unsafe or impractical;

(2) Vehicles are not loaded beyond maximum passenger capacity at any time;

(3) Drivers do not back up or make U-turns, except when necessary for safety reasons or because of physical barriers;

(4) Stops are located to minimize traffic disruptions and to afford the driver a good field of view in front of and behind the vehicle;

(5) When possible, stops are located to eliminate the need for children to cross the street or highway to board or leave the vehicle;

(6) Either a bus monitor or another adult escorts children across the street to board or leave the vehicle if curbside pick-up or drop off is impossible; and,

(7) Drivers use alternate routes in the case of hazardous conditions that could affect the safety of the children who are being transported, such as ice or water build up, natural gas line breaks, or emergency road closing.

§ 1303.74 Safety procedures.

(a) A program must ensure children who receive transportation services are taught safe riding practices, safety procedures for boarding and leaving the vehicle and for crossing the street to and from the vehicle at stops, recognition of the danger zones around the vehicle, and emergency evacuation procedures, including participating in an emergency evacuation drill conducted on the vehicle the child will be riding.

(b) A program that provides transportation services must ensure at least two bus evacuation drills in addition to the one required under paragraph (a) of this section are conducted during the program year.

§ 1303.75 Children with disabilities.

(a) A program must ensure there are school buses or allowable alternate vehicles adapted or designed for transportation of children with disabilities available as necessary to transport such children enrolled in the program. This requirement does not apply to the transportation of children receiving home-based services unless school buses or allowable alternate vehicles are used to transport the other children served under the home-based option by the grantee. Whenever possible, children with disabilities must be transported in the same vehicles used to transport other children enrolled in the Head Start or Early Head Start program.

(b) A program must ensure special transportation requirements in a child's IEP or IFSP are followed, including special pick-up and drop-off requirements, seating requirements, equipment needs, any assistance that may be required, and any necessary training for bus drivers and monitors.

PART 1304—FEDERAL ADMINISTRATIVE PROCEDURES

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Authority: 42 U.S.C. 9801 *et seq.*

Subpart A—Monitoring, Suspension, Termination, Denial of Refunding, Reduction in Funding, and Their Appeals

§ 1304.1 Purpose.

(a) Section 641A(c) of the Act requires the Secretary to monitor whether a grantee meets program governance, program operations, and financial and administrative standards described in this regulation and to identify areas for improvements and areas of strength as part of the grantee's ongoing self-assessment process. This subpart focuses on the monitoring process. It discusses areas of noncompliance, deficiencies, and corrective action through quality improvement plans.

(b) Section 646(a) of the Act requires the Secretary to prescribe procedures for notice and appeal for certain adverse actions. This subpart establishes rules and procedures to suspend financial assistance to a grantee, deny a grantee's application for refunding, terminate, or reduce a grantee's assistance under the Act when the grantee improperly uses federal funds or fails to comply with applicable laws, regulations, policies, instructions, assurances, terms and conditions or, if the grantee loses its legal status or financial viability. This subpart does not apply to reductions to a grantee's financial assistance based on chronic under-enrollment procedures at section 641A(h) of the Act or to matters described in subpart B. This subpart does not apply to any administrative action based upon any violation, or alleged violation, of title VI of the Civil Rights Act of 1964. Except as otherwise provided for in this subpart, the appeals and processes in this subpart will be governed by the Departmental Appeals Board regulations at 45 CFR part 16.

§ 1304.2 Monitoring.

(a) *Areas of noncompliance.* If a responsible HHS official determines through monitoring, pursuant to section 641(A)(c)(1) and (2) of the Act, that a grantee fails to comply with any of the standards described in parts 1301, 1302, and 1303 of this chapter, the official will notify the grantee promptly in writing, identify the area of noncompliance, and specify when the grantee must correct the area of noncompliance.

(b) *Deficiencies.* If the Secretary determines that a grantee meets one of the criteria for a deficiency, as defined in section 637(2)(C) of the Act, the Secretary shall inform the grantee of the deficiency. The grantee must correct the deficiency pursuant to section 641A(e)(1)(B) of the Act, as the responsible HHS official determines.

(c) *Quality improvement plans.* If the responsible HHS official does not require the grantee to correct a deficiency immediately as prescribed under section 641A(e)(1)(B)(i) of the Act, the grantee must submit to the official, for approval, a quality improvement plan that adheres to section 641A(e)(2)(A) of the Act.

§ 1304.3 Suspension with notice.

(a) *Grounds to suspend financial assistance with notice.* If a grantee breaches or threatens to breach any requirement stated in §§ 1304.3 through 1304.5, the responsible HHS official may suspend the grantee's financial assistance, in whole or in part, after it has given the grantee notice and an opportunity to show cause why assistance should not be suspended.

(b) *Notice requirements.* (1) The responsible HHS official must notify the grantee in writing that ACF intends to suspend financial assistance, in whole or in part. The notice must:

(i) Specify grounds for the suspension;

(ii) Include the date suspension will become effective;

(iii) Inform the grantee that it has the opportunity to submit to the responsible HHS official, at least seven days before suspension becomes effective, any written material it would like the official to consider, and to inform the grantee that it may request, in writing, no later than seven days after the suspension notice was mailed, to have an informal meeting with the responsible HHS official;

(iv) Invite the grantee to voluntarily correct the deficiency; and,

(v) Include a copy of this subpart.

(2) The responsible HHS official must promptly transmit the suspension notice to the grantee. The notice becomes effective when the grantee receives the notice, when the grantee refuses delivery, or when the suspension notice is returned to sender unclaimed.

(3) The responsible HHS official must send a copy of the suspension notice to any delegate agency whose actions or whose failures to act substantially caused or contributed to the proposed suspension. The responsible HHS official will inform the delegate agency that it is entitled to submit written material to oppose the suspension and to participate in the informal meeting, if one is held. In addition, the responsible HHS official may give notice to the grantee's other delegate agencies.

(4) After the grantee receives the suspension notice, it has three days to send a copy of the notice to delegate agencies that would be financially affected by a suspension.

(c) *Opportunity to show cause.* The grantee may submit to the responsible HHS official any written material to show why financial assistance should not be suspended. The grantee may also request, in writing, to have an informal meeting with the responsible HHS official. If the grantee requests an informal meeting, the responsible HHS official must schedule the meeting within seven days after the grantee receives the suspension notice.

(d) *Extensions.* If the responsible HHS official extends the time or the date by which a grantee has to make requests or to submit material, it must notify the grantee in writing.

(e) *Decision.* (1) The responsible HHS official will consider any written material presented before or during the informal meeting, as well as any proof the grantee has adequately corrected what led to suspension, and will render a decision within five days after the informal meeting. If no informal meeting is held, the responsible HHS official will render a decision within five days after it receives written material from all concerned parties.

(2) If the responsible HHS official finds the grantee failed to show cause why ACF should not suspend financial assistance, the official may suspend financial assistance, in whole or in part, and under terms and conditions as he or she deems appropriate.

(3) A suspension must not exceed 30 days, unless the conditions under section 646(a)(5)(B) are applicable or the grantee requests the suspension continue for an additional period of time and the responsible HHS official agrees.

(4) The responsible HHS official may appoint an agency to serve as an interim grantee to operate the program until the grantee's suspension is lifted, or as otherwise provided under section 646(a)(5)(B) of the Act.

(f) *Obligations incurred during suspension.* New obligations the grantee incurs while under suspension are not allowed unless the responsible HHS official expressly authorizes them in the suspension notice or in an amendment to the suspension notice. Necessary and otherwise allowable costs which the grantee could not reasonably avoid during the suspension period will be allowed if they result from obligations the grantee properly incurred before suspension and not in anticipation of suspension or termination. The responsible HHS official may allow third-party in-kind contributions applicable to the suspension period to satisfy cost sharing or matching requirements.

(g) *Modify or rescind suspension.* The responsible HHS official may modify or rescind suspension at any time, if the grantee can satisfactorily show that it has adequately corrected what led to suspension and that it will not repeat such actions or inactions. Nothing in this section precludes the HHS official from imposing suspension again for additional 30 day periods if the cause of the suspension has not been corrected.

§ 1304.4 Emergency suspension without advance notice.

(a) *Grounds to suspend financial assistance without advance notice.* The responsible HHS official may suspend financial assistance, in whole or in part, without prior notice and an opportunity to show cause if there is an emergency situation, such as a serious risk for substantial injury to property or loss of project funds, a federal, state, or local criminal statute violation, or harm to staff or participants' health and safety.

(b) *Emergency suspension notification requirements.* (1) The emergency suspension notification must:

(i) Specify the grounds for the suspension;

(ii) Include terms and conditions of any full or partial suspension;

(iii) Inform that grantee it cannot make or incur any new expenditures or obligations under suspended portion of the program; and,

(iv) Advise that within five days after the emergency suspension becomes effective, the grantee may request, in writing, an informal meeting with the responsible HHS official to show why the basis for the suspension was not valid and should be rescinded and that the grantee has corrected any deficiencies.

(2) The responsible HHS official must promptly transmit the emergency suspension notification to the grantee that shows the date of receipt. The emergency suspension becomes effective upon delivery of the notification or upon the date the grantee refuses delivery, or upon return of the notification unclaimed.

(3) Within two workdays after the grantee receives the emergency suspension notification, the grantee must send a copy of the notice to delegate agencies affected by the suspension.

(4) The responsible HHS official must inform affected delegate agencies that they have the right to participate in the informal meeting.

(c) *Opportunity to show cause.* If the grantee requests an informal meeting, the responsible HHS official must schedule a meeting within five workdays after it receives the grantee's request. The suspension will continue until the grantee has been afforded such opportunity and until the responsible HHS official renders a decision. Notwithstanding provisions in this section, the responsible HHS official may proceed to deny refunding or to initiate termination proceedings at any time even though the grantee's financial assistance has been suspended in whole or in part.

(d) *Decision.* (1) The responsible HHS official will consider any written material presented before or during the informal meeting, as well as any proof the grantee has adequately corrected what led to suspension, and render a decision within five work days after the informal meeting.

(2) If the responsible HHS official finds the grantee failed to show cause why suspension should be rescinded, the responsible HHS official may continue the suspension, in whole or in part, and under the terms and conditions specified in the emergency suspension notification.

(3) A suspension must not exceed 30 days, unless the conditions under section 646(a)(5)(B) are applicable or the grantee requests the suspension to continue for an additional period of time and the responsible HHS official agrees.

(4) The responsible HHS official may appoint an agency to serve as an interim grantee to operate the program until either the grantee's emergency suspension is lifted or a new grantee is selected.

(e) *Obligations incurred during suspension.* Any new obligations the grantee incurs during the suspension period will not be allowed unless the responsible HHS official expressly authorizes them in the suspension notice or in an amendment to the suspension notice. Necessary and otherwise allowable costs which the grantee could not reasonably avoid during the suspension period will be allowed if those costs result from obligations properly incurred before suspension and not in anticipation of suspension, denial of refunding or termination. The responsible HHS official may allow third-party in-kind contributions applicable to the suspension period to satisfy cost sharing or matching requirements.

(f) *Modify or rescind suspension.* The responsible HHS official may modify or rescind suspension at any time, if the grantee can satisfactorily show that is has adequately corrected what led to the suspension and that it will not repeat such actions or inactions. Nothing in this section precludes the HHS official from imposing suspension again for additional 30 day periods if the cause of the suspension has not been corrected.

§ 1304.5 Termination and denial of refunding.

(a) *Grounds to terminate financial assistance or deny a grantee's application for refunding.* (1) A responsible HHS official may terminate financial assistance in whole or in part to a grantee or deny a grantee's application for refunding.

(2) The responsible HHS official may terminate financial assistance in whole or in part, or deny refunding to a grantee for any one or for all of the following reasons:

(i) The grantee is no longer financially viable;

(ii) The grantee has lost the requisite legal status or permits;

(iii) The grantee has failed to timely correct one or more deficiencies as defined in the Act;

(iv) The grantee has failed to comply with eligibility requirements;

(v) The grantee has failed to comply with the Head Start grants administration or fiscal requirements set forth in 45 CFR part 1303;

(vi) The grantee has failed to comply with requirements in the Act;

(vii) The grantee is debarred from receiving federal grants or contracts; or

(viii) The grantee has failed to abide by any other terms and conditions of its award of financial assistance, or any other applicable laws, regulations, or other applicable federal or state requirements or policies.

(b) *Notice requirements.* (1) The responsible HHS official will notify the grantee and such notice will:

(i) Include the legal basis for termination or adverse action as described in paragraph (a) of this section;

(ii) Include factual findings on which the action is based or reference specific findings in another document that form the basis for termination or denial of refunding;

(iii) Cite to any statutory provisions, regulations, or policy issuances on which ACF relies for its determination;

(iv) Inform the grantee that it may appeal the denial or termination within 30 days to the Departmental Appeals Board, that the appeal will be governed by 45 CFR part 16, except as otherwise provided in the Head Start appeals regulations, that a copy of the appeal must sent to the responsible HHS official, and that it has the right to request and receive a hearing, as mandated under section 646 of the Act;

(v) Inform the grantee that only its board of directors, or an official acting on the board's behalf can appeal the decision;

(vi) Name the delegate agency, if the actions of that delegate are the basis, in whole or in part, for the proposed action; and,

(vii) Inform the grantee that the appeal must meet requirements in paragraph (c) of this section; and, that if the responsible HHS official fails to meet requirements in this paragraph, the pending action may be dismissed without prejudice or remanded to reissue it with corrections.

(2) The responsible HHS official must provide the grantee as much notice as possible, but must notify the grantee no later than 30 days after ACF receives the annual application for refunding, that it has the opportunity for a full and fair hearing on whether refunding should be denied.

(c) *Grantee's appeal.* (1) The grantee must adhere to procedures and requirements for appeals in 45 CFR part 16, file the appeal with the Departmental Appeals Board, and serve a copy of the appeal on the responsible HHS official who issued the termination or denial of refunding notice. The grantees must also serve a copy of its appeal on any affected delegate.

(2) Unless funding has been suspended, funding will continue while a grantee appeals a termination decision, unless the responsible HHS official renders an adverse decision, or unless the current budget period is expired. If the responsible HHS official has not rendered a decision by the end of the current budget period, the official will award the grantee interim funding until a decision is made or the project period ends.

(d) *Funding during suspension.* If a grantee's funding is suspended, the grantee will not receive funding during the termination proceedings, or at any other time, unless the action is rescinded or the grantee's appeal is successful.

(e) *Interim and replacement grantees.* The responsible HHS official may appoint an interim or replacement grantee as soon as a termination action is affirmed by the Departmental Appeals Board.

(f) *Opportunity to show cause.* (1) If the Departmental Appeals Board sets a hearing for a proposed termination or denial of refunding action, the grantee has five workdays to send a copy of the notice it receives from the Departmental Appeals Board, to all delegate agencies that would be financially affected by termination and to each delegate agency identified in the notice.

(2) The grantee must send to the Departmental Appeals Board and to the responsible HHS official a list of the delegate agencies it notified and the dates when it notified them.

(3) If the responsible HHS official initiated proceedings because of a delegate agency's activities, the official must inform the delegate agency that it may participate in the hearing. If the delegate agency chooses to participate in the hearing, it must notify the responsible HHS official in writing within 30 days of the grantee's appeal. If any other delegate agency, person, agency or organization wishes to participate in the hearing, it may request permission to do so from the Departmental Appeals Board.

(4) If the grantee fails to appear at the hearing, without good cause, the grantee will be deemed to have waived its right to a hearing and consented to have the Departmental Appeals Board make a decision based on the parties' written information and argument.

(5) A grantee may waive the hearing and submit written information and argument for the record, within a reasonable period of time to be fixed by the Departmental Appeals Board.

(6) The responsible HHS official may attempt, either personally or through a representative, to resolve the issues in dispute by informal means prior to the hearing.

(g) *Decision.* The Departmental Appeals Board's decision and any measure the responsible HHS official takes after the decision is fully binding upon the grantee and its delegate agencies, whether or not they actually participated in the hearing.

§ 1304.6 Appeal for prospective delegate agencies.

(a) *Appeal.* If a grantee denies, or fails to act on, a prospective delegate agency's funding application, the prospective delegate may appeal the grantee's decision or inaction.

(b) *Process for prospective delegates.* To appeal, a prospective delegate must:

(1) Submits the appeal, including a copy of the funding application, to the responsible HHS official within 30 days after it receives the grantee's decision; or within 30 days after the grantee has had 120 days to review but has not notified the applicant of a decision; and,

(2) Provide the grantee with a copy of the appeal at the same time the appeal is filed with the responsible HHS official.

(c) *Process for grantees.* When an appeal is filed with the responsible HHS official, the grantee must respond to the appeal and submit a copy of its response to the responsible HHS official and to the prospective delegate agency within 30 work days.

(d) *Decision.* (1) The responsible HHS official will sustain the grantee's decision, if the official determines the grantee did not act arbitrarily, capriciously, or otherwise contrary to law, regulation, or other applicable requirements.

(2) The responsible HHS official will render a written decision to each party within a reasonable timeframe. The

official's decision is final and not subject to further appeal.

(3) If the responsible HHS official finds the grantee did act arbitrarily, capriciously, or otherwise contrary to law, regulation, or other applicable requirements, the grantee will be directed to reevaluate their applications.

§ 1304.7 Legal fees.

(a) An agency is not authorized to charge to its grant legal fees or other costs incurred to appeal terminations, reductions of funding, or denials of applications of refunding decisions.

(b) If a program prevails in a termination, reduction, or denial of refunding decision, the responsible HHS official may reimburse the agency for reasonable and customary legal fees, incurred during the appeal, if:

(1) The Departmental Appeals Board overturns the responsible HHS official's decision;

(2) The agency can prove it incurred fees during the appeal; and,

(3) The agency can prove the fees incurred are reasonable and customary.

Subpart B—Designation Renewal

§ 1304.10 Purpose and scope.

The purpose of this subpart is to set forth policies and procedures for the designation renewal of Head Start and Early Head Start programs. It is intended that these programs be administered effectively and responsibly; that applicants to administer programs receive fair and equitable consideration; and that the legal rights of current Head Start and Early Head Start grantees be fully protected. The Designation Renewal System is established in this part to determine whether Head Start and Early Head Start agencies deliver high-quality services to meet the educational, health, nutritional, and social needs of the children and families they serve; meet the program and financial requirements and standards described in section 641A(a)(1) of the Head Start Act; and qualify to be designated for funding for five years without competing for such funding as required under section 641(c) of the Head Start Act with respect to Head Start agencies and pursuant to section 645A(b)(12) and (d) with respect to Early Head Start agencies. A competition to select a new Head Start or Early Head Start agency to replace a Head Start or Early Head Start agency that has been terminated voluntarily or involuntarily is not part of the Designation Renewal System established in this Part, and is subject instead to the requirements of § 1304.20.

§ 1304.11 Basis for determining whether a Head Start agency will be subject to an open competition.

A Head Start or Early Head Start agency shall be required to compete for its next five years of funding whenever the responsible HHS official determines that one or more of the following seven conditions existed during the relevant time period covered by the responsible HHS official's review under § 1304.15:

(a) An agency has been determined by the responsible HHS official to have one or more deficiencies on a single review conducted under section 641A(c)(1)(A), (C), or (D) of the Act in the relevant time period covered by the responsible HHS official's review under § 1304.15.

(b) An agency has been determined by the responsible HHS official based on a review conducted under section 641A(c)(1)(A), (C), or (D) of the Act during the relevant time period covered by the responsible HHS official's review under § 1304.15 not to have:

(1) After December 9, 2011, established program goals for improving the school readiness of children participating in its program in accordance with the requirements of section 641A(g)(2) of the Act and demonstrated that such goals:

(i) Appropriately reflect the ages of children, birth to five, participating in the program;

(ii) Align with the Birth to Five Head Start Child Outcomes Framework, state early learning guidelines, and the requirements and expectations of the schools, to the extent that they apply to the ages of children, birth to five, participating in the program and at a minimum address the domains of language and literacy development, cognition and general knowledge, approaches toward learning, physical well-being and motor development, and social and emotional development;

(iii) Were established in consultation with the parents of children participating in the program.

(2) After December 9, 2011, taken steps to achieve the school readiness goals described under paragraph (b)(1) of this section demonstrated by:

(i) Aggregating and analyzing aggregate child-level assessment data at least three times per year (except for programs operating less than 90 days, which will be required to do so at least twice within their operating program period) and using that data in combination with other program data to determine grantees' progress toward meeting its goals, to inform parents and the community of results, and to direct continuous improvement related to curriculum, instruction, professional development, program design and other program decisions; and,

(ii) Analyzing individual ongoing, child-level assessment data for all children birth to age five participating in the program and using that data in combination with input from parents and families to determine each child's status and progress with regard to, at a minimum, language and literacy development, cognition and general knowledge, approaches toward learning, physical well-being and motor development, and social and emotional development and to individualize the experiences, instructional strategies, and services to best support each child.

(c) An agency has been determined during the relevant time period covered by the responsible HHS official's review under § 1304.15:

(1) After December 9, 2011, to have an average score across all classrooms observed below the following minimum thresholds on any of the three CLASS: Pre-K domains from the most recent CLASS: Pre-K observation:

(i) For the Emotional Support domain the minimum threshold is 4;

(ii) For the Classroom Organization domain, the minimum threshold is 3;

(iii) For the Instructional Support domain, the minimum threshold is 2;

(2) After December 9, 2011, to have an average score across all classrooms observed that is in the lowest 10 percent on any of the three CLASS: Pre-K domains from the most recent CLASS: Pre-K observation among those currently being reviewed unless the average score across all classrooms observed for that CLASS: Pre-K domain is equal to or above the standard of excellence that demonstrates that the classroom interactions are above an exceptional level of quality. For all three domains, the "standard of excellence" is a 6.

(d) An agency has had a revocation of its license to operate a Head Start or Early Head Start center or program by a state or local licensing agency during the relevant time period covered by the responsible HHS official's review under § 1304.15, and the revocation has not been overturned or withdrawn before a competition for funding for the next five-year period is announced. A pending challenge to the license revocation or restoration of the license after correction of the violation shall not affect application of this requirement after the competition for funding for the next five-year period has been announced.

(e) An agency has been suspended from the Head Start or Early Head Start program by ACF during the relevant time period covered by the responsible

HHS official's review under § 1304.16 and the suspension has not been overturned or withdrawn. If there is a pending appeal and the agency did not have an opportunity to show cause as to why the suspension should not have been imposed or why the suspension should have been lifted if it had already been imposed under this part, the agency will not be required to compete based on this condition. If an agency has received an opportunity to show cause, the condition will be implemented regardless of appeal status.

(f) An agency has been debarred from receiving federal or state funds from any federal or state department or agency or has been disqualified from the Child and Adult Care Food Program (CACFP) any time during the relevant time period covered by the responsible HHS official's review under § 1304.15 but has not yet been terminated or denied refunding by ACF. (A debarred agency will only be eligible to compete for Head Start funding if it receives a waiver described in 2 CFR 180.135.)

(g) An agency has been determined within the twelve months preceding the responsible HHS official's review under § 1304.15 to be at risk of failing to continue functioning as a going concern. The final determination is made by the responsible HHS official based on a review of the findings and opinions of an audit conducted in accordance with section 647 of the Act; an audit, review or investigation by a state agency; a review by the National External Audit Review (NEAR) Center; or an audit, investigation or inspection by the Department of Health and Human Services Office of Inspector General.

§ 1304.12 Grantee reporting requirements concerning certain conditions.

(a) Head Start agencies must report in writing to the responsible HHS official within 30 working days of December 9, 2011, if the agency has had a revocation of a license to operate a center by a state of local licensing entity during the period between June 12, 2009, and December 9, 2011.

(b) Head Start agencies must report in writing to the responsible HHS official within 10 working days of occurrence any of the following events following December 9, 2011:

(1) The agency has had a revocation of a license to operate a center by a state or local licensing entity.

(2) The agency has filed for bankruptcy or agreed to a reorganization plan as part of a bankruptcy settlement.

(3) The agency has been debarred from receiving federal or state funds from any federal or state department or agency or has been disqualified from the Child and Adult Care Food Program (CACFP).

(4) The agency has received an audit, audit review, investigation or inspection report from the agency's auditor, a state agency, or the cognizant federal audit agency containing a determination that the agency is at risk for ceasing to be a going concern.

§ 1304.13 Requirements to be considered for designation for a five-year period when the existing grantee in a community is not determined to be delivering a high-quality and comprehensive Head Start program and is not automatically renewed.

In order to compete for the opportunity to be awarded a five-year grant, an agency must submit an application to the responsible HHS official that demonstrates that it is the most qualified entity to deliver a high-quality and comprehensive Head Start or Early Head Start program. The application must address the criteria for selection listed at section 641(d)(2) of the Act for Head Start. Any agency that has had its Head Start or Early Head Start grant terminated for cause in the preceding five years is excluded from competing in such competition for the next five years. A Head Start or Early Head Start agency that has had a denial of refunding, as defined in 45 CFR part 1305, in the preceding five years is also excluded from competing.

§ 1304.14 Tribal government consultation under the Designation Renewal System for when an Indian Head Start grant is being considered for competition.

(a) In the case of an Indian Head Start or Early Head Start agency determined not to be delivering a high-quality and comprehensive Head Start or Early Head Start program, the responsible HHS official will engage in government-to-government consultation with the appropriate tribal government or governments for the purpose of establishing a plan to improve the quality of the Head Start program or Early Head Start program operated by the Indian Head Start or Indian Early Head Start agency.

(1) The plan will be established and implemented within six months after the responsible HHS official's determination.

(2) Not more than six months after the implementation of that plan, the responsible HHS official will reevaluate the performance of the Indian Head Start or Early Head Start agency.

(3) If the Indian Head Start or Early Head Start agency is still not delivering a high-quality and comprehensive Head Start or Early Head Start program, the responsible HHS official will conduct an open competition to select a grantee to provide services for the community currently being served by the Indian Head Start or Early Head Start agency.

(b) A non-Indian Head Start or Early Head Start agency will not be eligible to receive a grant to carry out an Indian Head Start program, unless there is no Indian Head Start or Early Head Start agency available for designation to carry out an Indian Head Start or Indian Early Head Start program.

(c) A non-Indian Head Start or Early Head Start agency may receive a grant to carry out an Indian Head Start program only until such time as an Indian Head Start or Indian Early Head Start agency in such community becomes available and is designated pursuant to this part.

§ 1304.15 Designation request, review and notification process.

(a) Grantees must apply to be considered for Designation Renewal.

(1) For the transition period, each Head Start or Early Head Start agency wishing to be considered to have their designation as a Head Start or Early Head Start agency renewed for a five year period without competition shall request that status from ACF within six months of December 9, 2011.

(2) After the transition period, each Head Start or Early Head Start agency wishing to be considered to have their designation as a Head Start or Early Head Start agency renewed for another five year period without competition shall request that status from ACF at least 12 months before the end of their five year grant period or by such time as required by the Secretary.

(b) ACF will review the relevant data to determine if one or more of the conditions under § 1304.11 were met by the Head Start and Early Head Start agency's program:

(1) During the first year of the transition period, ACF shall review the data on each Head Start and Early Head Start agency to determine if any of the conditions under § 1304.11(a) or (d) through (g) were met by the agency's program since June 12, 2009.

(2) During the remainder of the transition period, ACF shall review the data on each Head Start and Early Head Start agency still under grants with indefinite project periods and for whom ACF has relevant data on all of the conditions in § 1304.11(a) through (g) to determine if any of the conditions under § 1304.11(a) or (d) through (g) were met by the agency's program since June 12, 2009, or if the conditions under § 1304.11(b) or (c) existed in the agency's program since December 9, 2011.

(3) Following the transition period, ACF shall review the data on each Head Start and Early Head Start agency in the fourth year of the grant to determine if any of the conditions under § 1304.11 existed in the agency's program during the period of that grant.

(c) ACF will give notice to grantees on Designation Renewal System status, except as provided in § 1304.14:

(1) During the first year of the transition period, ACF shall give written notice to all grantees meeting any of the conditions under § 1304.11(a) or (d) through (g) since June 12, 2009, by certified mail return receipt requested or other system that establishes the date of receipt of the notice by the addressee, stating that the Head Start or Early Head Start agency will be required to compete for funding for an additional five-year period, identifying the conditions ACF found, and summarizing the basis for the finding. All grantees that do not meet any of the conditions under § 1304.11(a) or (d) through (g) will remain under indefinite project periods until the time period described under paragraph (b)(2) of this section.

(2) During the remainder of the transition period, ACF shall give written notice to all grantees still under grants with indefinite project periods and on the conditions in § 1304.11(a) through (g) by certified mail return receipt requested or other system that establishes the date of receipt of the notice by the addressee stating either:

(i) The Head Start or Early Head Start agency will be required to compete for funding for an additional five-year period because ACF finds that one or more conditions under § 1304.11(a) through (g) has been met during the relevant time period described in paragraph (b) of this section, identifying the conditions ACF found, and summarizing the basis for the finding; or

(ii) That such agency has been determined on a preliminary basis to be eligible for renewed funding for five years without competition because ACF finds that none of the conditions under § 1304.11 have been met during the relevant time period described in paragraph (b) of this section. If prior to the award of that grant, ACF determines that the grantee has met one of the conditions under § 1304.11 during the relevant time period described in paragraph (b) of this section, this determination will change and the grantee will receive notice under paragraph (c)(2)(i) of this section that it will be required to compete for funding for an additional five-year period.

(3) Following the transition period, ACF shall give written notice to all grantees at least 12 months before the expiration date of a Head Start or Early Head Start agency's then current grant by certified mail return receipt requested or other system that establishes the date of receipt of the notice by the addressee, stating:

(i) The Head Start or Early Head Start agency will be required to compete for funding for an additional five-year period because ACF finds that one or more conditions under § 1304.11 were met by the agency's program during the relevant time period described in paragraph (b) of this section, identifying the conditions ACF found, and summarizing the basis for the finding; or,

(ii) That such agency has been determined on a preliminary basis to be eligible for renewed funding for five years without competition because ACF finds that none of the conditions under § 1304.11 have been met during the relevant time period described in paragraph (b) of this section. If prior to the award of that grant, ACF determines that the grantee has met one of the conditions under § 1304.11 during the relevant time period described in paragraph (b) of this section, this determination will change and the grantee will receive notice under paragraph (c)(3)(i) of this section that it will be required to compete for funding for an additional five-year period.

§ 1304.16 Use of CLASS: Pre-K instrument in the Designation Renewal System.

Except when all children are served in a single classroom, ACF will conduct observations of multiple classes operated by the grantee based on a random sample of all classes and rate the conduct of the classes observed using the CLASS: Pre-K instrument. When the grantee serves children in its program in a single class, that class will be observed and rated using the CLASS: Pre-K instrument. The domain scores for that class will be the domain scores for the grantee for that observation. After the observations are completed, ACF will report to the grantee the scores of the classes observed during the CLASS: Pre-K observations in each of the domains covered by the CLASS: Pre-K instrument. ACF will average CLASS: Pre-K instrument scores in each domain for the classes operated by the agency that ACF observed to determine the agency's score in each domain.

Subpart C—Selection of Grantees Through Competition

§ 1304.20 Selection among applicants.

(a) In selecting an agency to be designated to provide Head Start, Early Head Start, Migrant or Seasonal Head Start or tribal Head Start or Early Head Start services, the responsible HHS official will consider the applicable criteria at Section 641(d) of the Head Start Act and any other criteria outlined in the funding opportunity announcement.

(b) In competitions to replace or potentially replace a grantee the responsible HHS official will also consider the extent to which the applicant supports continuity for participating children, the community and the continued employment of effective, well qualified personnel.

(c) In competitions to replace or potentially replace a current grantee, the responsible HHS official will give priority to applicants that have demonstrated capacity in providing effective, comprehensive, and well-coordinated early childhood education and development services and programs to children and their families.

Subpart D—Replacement of American Indian and Alaska Native Grantees

§1304.30 Procedure for indentification of alternative agency.

(a) An Indian tribe whose Head Start grant has been terminated, relinquished, designated for competition or which has been denied refunding as a Head Start agency, may identify an alternate agency and request the responsible HHS official to designate such agency as an alternative agency to provide Head Start services to the tribe if:

(1) The tribe was the only agency that was receiving federal financial assistance to provide Head Start services to members of the tribe; and,

(2) The tribe would be otherwise precluded from providing such services to its members because of the termination or denial of refunding.

(b)(1) The responsible HHS official, when notifying a tribal grantee of the intent to terminate financial assistance or deny its application for refunding, or its designation for competition must notify the grantee that it may identify an agency and request that the agency serve as the alternative agency in the event that the grant is terminated or refunding denied, or the grant is not renewed without competition.

(2) The tribe must identify the alternate agency to the responsible HHS official in writing.

(3) The responsible HHS official will notify the tribe, in writing, whether the alternative agency proposed by the tribe is found to be eligible for Head Start funding and capable of operating a Head Start program. If the alternative agency identified by the tribe is not an eligible agency capable of operating a Head Start

program, the tribe will have 15 days from the date of the sending of the notification to that effect from the responsible HHS official to identify another agency and request that the agency be designated. The responsible HHS official will notify the tribe in writing whether the second proposed alternate agency is found to be an eligible agency capable of operating the Head Start program.

(4) If the tribe does not identify an eligible, suitable alternative agency, a grantee will be designated under these regulations.

(c) If the tribe appeals a termination of financial assistance or a denial of refunding, it will, consistent with the terms of § 1304.5, continue to be funded pending resolution of the appeal. However, the responsible HHS official and the grantee will proceed with the steps outlined in this regulation during the appeal process.

(d) If the tribe does not identify an agency and request that the agency be appointed as the alternative agency, the responsible HHS official will seek a permanent replacement grantee under these regulations.

§ 1304.31 Requirements of alternative agency.

The agency identified by the Indian tribe must establish that it meets all requirements established by the Head Start Act and these requirements for designation as a Head Start grantee and that it is capable of conducting a Head Start program. The responsible HHS official, in deciding whether to designate the proposed agency, will analyze the capacity and experience of the agency according to the criteria found in section 641(d) of the Head Start Act and § 1304.20.

§ 1304.32 Alternative agency—prohibition.

(a) No agency will be designated as the alternative agency pursuant to this subpart if the agency includes an employee who:

(1) Served on the administrative or program staff of the Indian tribal grantee described under section 646(e)(1)(A) of the Act; and

(2) Was responsible for a deficiency that:

(i) Relates to the performance standards or financial management standards described in section 641A(a)(1) of the Act; and,

(ii) Was the basis for the termination of assistance under section 646(e)(1)(A) of the Act or denial of refunding described in § 1304.4.

(b) The responsible HHS official shall determine whether an employee was responsible for a deficiency within the meaning and context of this section.

Subpart E—Head Start Fellows Program

§ 1304.40 Purpose.

As provided in section 648A(d) of the Act, the Head Start Fellows Program is designed to enhance the ability of Head Start Fellows to make significant contributions to Head Start and to other child development and family services programs.

§ 1304.41 Fellows Program.

(a) *Selection.* An applicant must be working on the date of application in a local Head Start program or otherwise working in the field of child development and family services. The qualifications of the applicants for Head Start Fellowship positions will be competitively reviewed.

(b) *Placement.* Head Start Fellows may be placed in the Head Start national and regional offices; local Head Start agencies and programs; institutions of higher education; public or private entities and organizations concerned with services to children and families; and other appropriate settings.

(c) *Restrictions.* A Head Start Fellow who is not an employee of a local Head Start agency or program may only be placed in the national or regional offices within the Department of Health and Human Services that administer Head Start or local Head Start agencies. Head Start Fellows shall not be placed in any agency whose primary purpose, or one of whose major purposes is to influence federal, state or local legislation.

(d) *Duration.* Head Start Fellowships will be for terms of one year, and may be renewed for a term of one additional year.

(e) *Status.* For the purposes of compensation for injuries under chapter 81 of title 5, United States Code, Head Start Fellows shall be considered to be employees, or otherwise in the service or employment, of the federal government. Head Start Fellows assigned to the national or regional offices within the Department of Health and Human Services shall be considered employees in the Executive Branch of the federal government for the purposes of chapter 11 of title 18, United States Code, and for the purposes of any administrative standards of conduct applicable to the employees of the agency to which they are assigned.

PART 1305—DEFINITIONS

Sec.
1305.1 Purpose.
1305.2 Terms.

Authority: 42 U.S.C. 9801 *et seq.*

§ 1305.1 Purpose.

The purpose of this part is to define terms for the purposes of this subchapter.

§ 1305.2 Terms.

For the purposes of this subchapter, the following definitions apply:

ACF means the Administration for Children and Families in the Department of Health and Human Services.

Act means the Head Start Act, Sec. 635 *et seq.*, Public Law 97–35, 95 Stat. 499–511 (codified as amended at 42 U.S.C. Section 9801, *et seq.*).

Agency means the body that receives the Head Start grant.

Aggregate child-level assessment data means the data collected by an agency on the status and progress of the children it serves that have been combined to provide summary information about groups of children enrolled in specific classes, centers, home-based or other options, groups or settings, or other groups of children such as dual language learners, or to provide summary information by specific domains of development.

Allowable alternate vehicle means a vehicle designed for carrying eleven or more people, including the driver, that meets all the Federal Motor Vehicle Safety Standards applicable to school buses, except 49 CFR 571.108 and 571.131.

Budget period means the interval of time, into which a multi-year period of assistance (project period) is divided for budgetary and funding purposes.

Case plan is defined as presented in 42 U.S.C. 675(1) which, in summary, is a written document that must include a number of specified items including, but is not limited to, a plan for safe and proper care of the child in foster care placement, health records, and a plan for ensuring the educational stability of the child in foster care.

Child-level assessment data means the data collected by an agency on an individual child from one or more valid and reliable assessments of a child's status and progress, including but not limited to direct assessment, structured observations, checklists, staff or parent report measures, and portfolio records or work samples.

Child records means records that:

(1) Are directly related to the child;

(2) Are maintained by the program, or by a party acting for the program; and

(3) Include information recorded in any way, such as print, electronic, or digital means, including media, video, image, or audio format.

Child restraint system means any device designed to restrain, seat, or position children that meets the current requirements of Federal Motor Vehicle Safety Standard No. 213, Child Restraint Systems, 49 CFR 571.213, for children in the weight category established under the regulation, or any device designed to restrain, seat, or position children, other than a Type I seat belt as defined at 49 CFR 571.209, for children not in the weight category currently established by 49 CFR 571.213.

Child with a disability is defined in the same manner as presented in the Head Start Act, 42 U.S.C. 9801.

CLASS: Pre-K means The Classroom Assessment Scoring System (CLASS). The CLASS is an observational instrument that assesses classroom quality in preschool through third grade classrooms. This tool meets the requirements described in 641(c)(1)(D) and 641A(c)(2)(F) of the Head Start Act (42 U.S.C. 9836(c)(1)(D) and 9836a(c)(2)(F)). The CLASS assesses three domains of classroom experience: Emotional Support, Classroom Organization, and Instructional Support.

(1) Emotional Support measures children's social and emotional functioning in the classroom, and includes four dimensions: Positive Climate, Negative Climate, Teacher Sensitivity and Regard for Student Perspectives. Positive Climate addresses the emotional connection, respect, and enjoyment demonstrated between teachers and children and among children. Negative Climate addresses the level of expressed negativity such as anger, hostility, or aggression exhibited by teachers and/or children in the classroom. Teacher Sensitivity addresses teachers' awareness of and responsivity to children's academic and emotional concerns. Regard for Student Perspectives addresses the degree to which teachers' interactions with children and classroom activities place an emphasis on children's interests, motivations, and points of view.

(2) Classroom Organization measures a broad array of classroom processes related to the organization and management of children's behavior, time, and attention in the classroom. It includes three dimensions: Behavior Management, Productivity, and Instructional Learning Formats. Behavior Management addresses how effectively teachers monitor, prevent, and redirect behavior. Productivity addresses how well the classroom runs with respect to routines and the degree to which teachers organize activities and directions so that maximum time can be spent on learning activities. Instructional Learning Formats addresses how teachers facilitate activities and provide interesting materials so that children are engaged and learning opportunities are maximized.

(3) Instructional Support measures the ways in which teachers implement curriculum to effectively support cognitive and language development. It includes three dimensions: Concept Development, Quality of Feedback, and Language Modeling. Concept Development addresses how teachers use instructional discussions and activities to promote children's higher order thinking skills in contrast to a focus on rote instruction. Quality of Feedback addresses how teachers extend children's learning through their responses to children's ideas, comments, and work. Language Modeling addresses the extent to which teachers facilitate and encourage children's language.

(4) Assessments with the CLASS involve observation-based measurement of each dimension on a seven point scale. A score ranging from 1 (minimally characteristic) to 7 (highly characteristic) is given for each dimension and represents the extent to which that dimension is characteristic of that classroom. Relevant dimension scores are used to calculate each domain score.

Commercial Driver's License (CDL) means a license issued by a state or other jurisdiction, in accordance with the standards contained in 49 CFR part 383, to an individual which authorizes the individual to operate a class of commercial motor vehicles.

Construction means new buildings, and excludes renovations, alterations, additions, or work of any kind to existing buildings.

Continuity of care means Head Start or Early Head Start services provided to children in a manner that promotes primary caregiving and minimizes the number of transitions in teachers and teacher assistants that children experience over the course of the day, week, program year, and to the extent possible, during the course of their participation from birth to age three in Early Head Start and in Head Start.

Deficiency is defined in the same manner as presented in the Head Start Act, 42 U.S.C. 9801.

Delegate agency is defined in the same manner as presented in the Head Start Act, 42 U.S.C. 9801.

Development and administrative costs mean costs incurred in accordance with an approved Head Start budget which do not directly relate to the provision of program component services, including services to children with disabilities, as set forth and described in the Head Start program performance standards (45 CFR part 1304).

Disclosure means to permit access to or the release, transfer, or other communication of PII contained in child records by any means, including oral, written, or electronic means, to any party except the party identified as the party that provided or created the record.

Double session variation means a center-based option that employs a single teacher to work with one group of children in the morning and a different group of children in the afternoon.

Dual benefit costs mean costs incurred in accordance with an approved Head Start budget which directly relate to both development and administrative functions and to the program component services, including services to children with disabilities, as set forth and described in the Head Start program performance standards (45 CFR part 1304).

Dual language learner means a child who is acquiring two or more languages at the same time, or a child who is learning a second language while continuing to develop their first language. The term "dual language learner" may encompass or overlap substantially with other terms frequently used, such as bilingual, English language learner (ELL), Limited English Proficient (LEP), English learner, and children who speak a Language Other Than English (LOTE).

Early Head Start agency means a public or private non-profit or for-profit entity designated by ACF to operate an Early Head Start program to serve pregnant women and children from birth to age three, pursuant to Section 645A(e) of the Head Start Act.

Enrolled (or any variation of) means a child has been accepted and attended at least one class for center-based or family child care option or at least one home visit for the home-based option.

Enrollment year means the period of time, not to exceed twelve months, during which a Head Start program provides center or home-based services to a group of children and their families.

Facility means a structure, such as a building or modular unit, appropriate for use in carrying out a Head Start program and used primarily to provide Head Start services, including services to children and their families, or for administrative purposes or other activities necessary to carry out a Head Start program.

Family means all persons living in the same household who are supported by the child's parent(s)' or guardian(s)' income; and are related to the child's parent(s) or guardian(s) by blood, marriage, or adoption; or are the child's authorized caregiver or legally responsible party.

Federal interest is a property right which secures the right of the federal awarding agency to recover the current fair market value of its percentage of participation in the cost of the facility in the event the facility is no longer used for Head Start purposes by the grantee or upon the disposition of the property. When a grantee uses Head Start funds to purchase, construct or renovate a facility, or make mortgage payments, it creates a federal interest. The federal interest includes any portion of the cost of purchase, construction, or renovation contributed by or for the entity, or a related donor organization, to satisfy a matching requirement.

Federal Motor Vehicle Safety Standards (FMVSS) means the National Highway and Traffic Safety Administration's standards for motor vehicles and motor vehicle equipment (49 CFR part 571) established under section 30111 of Title 49, United States Code.

Financial viability means that an organization is able to meet its financial obligations, balance funding and expenses and maintain sufficient funding to achieve organizational goals and objectives.

Fixed route means the established routes to be traveled on a regular basis by vehicles that transport children to and from Head Start or Early Head Start program activities, and which include specifically designated stops where children board or exit the vehicle.

Foster care means 24-hour substitute care for children placed away from their parents or guardians and for whom the state agency has placement and care responsibility. This includes, but is not limited to, placements in foster family homes, foster homes of relatives, group homes, emergency shelters, residential facilities, child-care institutions, and pre-adoptive homes. A child is in foster care in accordance with this definition regardless of whether the foster care facility is licensed and payments are made by the state or local agency for the care of the child, whether adoption subsidy payments are being made prior to the finalization of an adoption, or whether there is federal matching of any payments that are made.

Full-working-day means not less than 10 hours of Head Start or Early Head Start services per day.

Funded enrollment means the number of participants which the Head Start grantee is to serve, as indicated on the grant award.

Going concern means an organization that operates *without* the threat of liquidation for the foreseeable future, a period of at least 12 months.

Grantee means the local public or private non-profit agency or for-profit agency which has been designated as a Head Start agency under 42 U.S.C. 9836 and which has been granted financial assistance by the responsible HHS official to operate a Head Start program.

Head Start agency means a local public or private non-profit or for-profit entity designated by ACF to operate a Head Start program to serve children age three to compulsory school age, pursuant to section 641(b) and (d) of the Head Start Act.

Head Start Early Learning Outcomes Framework: Ages Birth to Five means the *Head Start Early Learning Outcomes Framework: Ages Birth to Five,* which describes the skills, behaviors, and knowledge that programs must foster in all children. It includes five central domains: Approaches to Learning; Social and Emotional Development; Language and Literacy; Cognition; and Perceptual, Motor, and Physical Development. These central domains are broken into five domains for infants and toddlers and seven domains for preschoolers. Infant and Toddler domains are Approaches to Learning; Social and Emotional Development; Language and Communication; Cognition; and Perceptual, Motor, and Physical Development. Preschool domains are Approaches to Learning; Social and Emotional Development; Language and Communication; Literacy; Mathematics Development; Scientific Reasoning; and Perceptual, Motor, and Physical Development. Domains are divided into sub-domains with goals that describe broad skills, behaviors, and concepts that are important for school success. Developmental progressions describe the skills, behaviors and concepts that children may demonstrate as they progress. As described in the Head Start Act, the Framework is central to program operations that promote high-quality early learning environments (42 U.S.C. 9832(21)(G)(iv)(II)(aa), 42 U.S.C. 9835(o), 42 U.S.C. 9836(d)(2)(C), 42 U.S.C. 9836a(g)(2)(A), 42 U.S.C. 9837(f)(3)(E), 42 U.S.C. 9837a(a)(3), 42 U.S.C. 9837a(a)(14), 42 U.S.C. 9837b(a)(2)(B)(iii), 42 U.S.C. 9837b(a)(4)(A)(i), and 42 U.S.C. 9837b(a)(4)(B)(iii)).

Homeless children means the same as *homeless children and youths* in Section 725(2) of the McKinney-Vento Homeless Assistance Act at 42 U.S.C. 11434a(2).

Home visitor means the staff member in the home-based program option assigned to work with parents to provide comprehensive services to children and their families through home visits and group socialization activities.

Hours of planned class operations means hours when children are scheduled to attend. Professional development, training, orientation, teacher planning, data analysis, parent-teacher conferences, home visits, classroom sanitation, and transportation do not count toward the hours of planned class operations.

Income means gross cash income and includes earned income, military income (including pay and allowances, except those described in Section 645(a)(3)(B) of the Act), veteran's benefits, Social Security benefits, unemployment compensation, and public assistance benefits. Additional examples of gross cash income are listed in the definition of "income" which appears in U.S. Bureau of the Census, Current Population Reports, Series P–60–185 (available at *https://www2.census.gov/prod2/popscan/p60-185.pdf*).

Indian Head Start agency means a program operated by an Indian tribe (as defined by the Act) or designated by an Indian tribe to operate on its behalf.

Indian tribe is defined in the same manner as presented in the Head Start Act, 42 U.S.C. 9801.

Individualized Education Program is defined in the same manner as presented in the Individuals with Disabilities Education Act (20 U.S.C. 1400 *et seq.*).

Individualized Family Service Plan is defined in the same manner as presented in the Individuals with Disabilities Education Act (20 U.S.C. 1400 *et seq.*).

Legal status means the existence of an applicant or grantee as a public agency or organization under the law of the state in which it is located, or existence as a private nonprofit or for-profit agency or organization as a legal entity recognized under the law of the state in which it is located. Existence as a private non-profit agency or organization may be established under applicable state or federal law.

Local agency responsible for implementing IDEA means the early intervention service provider under Part C of IDEA and the local educational agency under Part B of IDEA.

Major renovation means any individual or collection renovation that has a cost equal to or exceeding $250,000. It excludes minor renovations and repairs except when they are included in a purchase application.

Migrant family means, for purposes of Head Start eligibility, a family with children under the age of compulsory school attendance who changed their residence by moving from one geographic location to another, either intrastate or interstate, within the preceding two years for the purpose of engaging in agricultural work and whose family income comes primarily from this activity.

Migrant or Seasonal Head Start Program means:

(1) With respect to services for migrant farm workers, a Head Start program that serves families who are engaged in agricultural labor and who have changed their residence from one geographic location to another in the preceding 2-year period; and,

(2) With respect to services for seasonal farmworkers, a Head Start program that serves families who are engaged primarily in seasonal agricultural labor and who have not changed their residence to another geographic location in the preceding 2-year period.

Minor renovation means improvements to facilities, which do not meet the definition of major renovation.

Modular unit means a portable prefabricated structure made at another location and moved to a site for use by a Head Start grantee to carry out a Head Start program, regardless of the manner or extent to which the modular unit is attached to underlying real property.

National Driver Register means the National Highway Traffic Safety Administration's automated system for assisting state driver license officials in obtaining information regarding the driving records of individuals who have been denied licenses for cause; had their licenses denied for cause, had their licenses canceled, revoked, or suspended for cause, or have been convicted of certain serious driving offenses.

Parent means a Head Start child's mother or father, other family member who is a primary caregiver, foster parent or authorized caregiver, guardian or the person with whom the child has been placed for purposes of adoption pending a final adoption decree.

Participant means a pregnant woman or child who is enrolled in and receives services from a Head Start, an Early Head Start, a Migrant or Seasonal Head Start, or an American Indian and Alaska Native Head Start program.

Personally identifiable information (PII) means any information that could identify a specific individual, including but not limited to a child's name, name of a child's family member, street address of the child, social security number, or other information that is linked or linkable to the child.

Program means a Head Start, Early Head Start, migrant, seasonal, or tribal program, funded under the Act and carried out by an agency, or delegate agency, to provide ongoing comprehensive child development services.

Program costs mean costs incurred in accordance with an approved Head Start budget which directly relate to the provision of program component services, including services to children with disabilities, as set forth and described in the Head Start Program Performance Standards (45 CFR part 1304).

Purchase means to buy an existing facility, including outright purchase, down payment or through payments made in satisfaction of a mortgage or other loan agreement, whether principal, interest or an allocated portion principal and/or interest. The use of grant funds to make a payment under a capital lease agreement, as defined in the cost principles, is a purchase subject to these provisions. Purchase also refers to an approved use of Head Start funds to continue paying the cost of purchasing facilities or refinance an existing loan or mortgage beginning in 1987.

Real property means land, including land improvements, buildings, structures and all appurtenances thereto, excluding movable machinery and equipment.

Recruitment area means that geographic locality within which a Head Start program seeks to enroll Head Start children and families. The recruitment area can be the same as the service area or it can be a smaller area or areas within the service area.

Relevant time period means:

(1) The 12 months preceding the month in which the application is submitted; or

(2) During the calendar year preceding the calendar year in which the application is submitted, whichever more accurately reflects the needs of the family at the time of application.

Repair means maintenance that is necessary to keep a Head Start facility in working condition. Repairs do not add significant value to the property or extend its useful life.

Responsible HHS official means the official of the Department of Health and Human Services who has authority to make grants under the Act.

School readiness goals mean the expectations of children's status and progress across domains of language and literacy development, cognition and general knowledge, approaches to learning, physical well-being and motor development, and social and emotional development that will improve their readiness for kindergarten.

School bus means a motor vehicle designed for carrying 11 or more persons (including the driver) and which complies with the Federal Motor Vehicle Safety Standards applicable to school buses.

Service area means the geographic area identified in an approved grant application within which a grantee may provide Head Start services.

Staff means paid adults who have responsibilities related to children and their families who are enrolled in programs.

State is defined in the same manner as presented in the Head Start Act, 42 U.S.C. 9801.

Termination of a grant or delegate agency agreement means permanent withdrawal of the grantee's or delegate agency's authority to obligate previously awarded grant funds before that authority would otherwise expire. It also means the voluntary relinquishment of that authority by the grantee or delegate agency. Termination does not include:

(1) Withdrawal of funds awarded on the basis of the grantee's or delegate agency's underestimate of the unobligated balance in a prior period;

(2) Refusal by the funding agency to extend a grant or award additional funds (such as refusal to make a competing or noncompeting continuation renewal, extension or supplemental award);

(3) Withdrawal of the unobligated balance as of the expiration of a grant; and

(4) Annulment, *i.e.*, voiding of a grant upon determination that the award was obtained fraudulently or was otherwise illegal or invalid from its inception.

Total approved costs mean the sum of all costs of the Head Start program approved for a given budget period by the Administration for Children and Families, as indicated on the Financial Assistance Award. Total approved costs consist of the federal share plus any approved non-federal match, including non-federal match above the statutory minimum.

Transition period means the three-year time period after December 9, 2011, on the Designation Renewal System during which ACF will convert all of the current continuous Head Start and Early Head Start grants into five-year grants after reviewing each grantee to determine if it meets any of the conditions under § 1304.12 of this chapter that require recompetition or if the grantee will receive its first five-year grant non-competitively.

Transportation services means the planned transporting of children to and from sites where an agency provides services funded under the Head Start Act. Transportation services can involve the pick-up and discharge of children at regularly scheduled times and pre-arranged sites, including trips between children's homes and program settings. The term includes services provided directly by the Head Start and Early Head Start grantee or delegate agency and services which such agencies arrange to be provided by another organization or an individual. Incidental trips, such as transporting a sick child home before the end of the day, or such as might be required to transport small groups of children to and from necessary services, are not included under the term.

Verify or any variance of the word means to check or determine the correctness or truth by investigation or by reference.

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Part III

Department of Health and Human Services

45 CFR Parts 144, 146, 147, 148, *et al.*
Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 146, 147, 148, 153, 154, 155, 156, 157, and 158

[CMS–9934–P]

RIN 0938–AS95

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth payment parameters and provisions related to the risk adjustment program; cost-sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges and State-based Exchanges on the Federal platform. It also provides additional guidance relating to standardized options; qualified health plans; consumer assistance tools; network adequacy; the Small Business Health Options Program; stand-alone dental plans; fair health insurance premiums; guaranteed renewability; the medical loss ratio program; eligibility and enrollment; appeals; and other related topics.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 6, 2016.

ADDRESSES: In commenting, please refer to file code CMS–9934–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9934–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9934–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.) b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Jeff Wu, (301) 492–4305, Lindsey Murtagh, (301) 492–4106, or Michelle Koltov, (301) 492–4225 for general information.

Lisa Cuozzo, (410) 786–1746, for matters related to fair health insurance premiums, guaranteed renewability, and single risk pool.

Michael Cohen, (301) 492–4277, for matters related to the Pre-Existing Condition Insurance Plan Program.

Kelly Drury, (410) 786–0558, or Krutika Amin, (301) 492–5153, for matters related to risk adjustment.

Adrianne Patterson, (410) 786–0686, for matters related to sequestration, risk adjustment data validation discrepancies, and administrative appeals.

Emily Ames, (301) 492–4246, for matters related to language access.

Dana Krohn, (301) 492–4412, for matters related to periodic data matching, redeterminations of advance payments of the premium tax credit, and appeals.

Ryan Mooney, (301) 492–4405, for matters related to premium payment, billing, and terminations due to fraud.

Christelle Jang, (410) 786–8438, for matters related to the Small Business Health Options Program (SHOP).

Krutika Amin, (301) 492–5153, for matters related to the Federally-facilitated Exchange user fee.

Leigha Basini, (301) 492–4380, for matters related to mid-year withdrawals, and other standards for QHP issuers.

Ielnaz Kashefipour, (301) 492–4376, for matters related to standardized options.

Rebecca Zimmermann, (301) 492–4396, for matters related to stand-alone dental plans.

Cindy Chiou, (301) 492–5142, for matters related to QHP issuer oversight and direct enrollment.

Allison Yadsko, (410) 786–1740, for matters related to levels of coverage and actuarial value.

Pat Meisol, (410) 786–1917, for matters related to cost-sharing reductions, reconciliation of the cost-sharing reduction portion of advance payments discrepancies, and the premium adjustment percentage.

Christina Whitefield, (301) 492–4172, for matters related to the medical loss ratio program.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Acronyms and Abbreviations

Affordable Care Act	The collective term for the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), as amended
APTC	Advance payments of the premium tax credit
AV	Actuarial value
CBO	Congressional Budget Office
CFR	Code of Federal Regulations
CHIP	Children's Health Insurance Program
CMP	Civil money penalties
CMS	Centers for Medicare & Medicaid Services
CPI	Consumer price index
ECP	Essential community provider
ED	Enrollment duration
EDGE	External data gathering environment
EHB	Essential health benefits
ESRD	End Stage Renal Disease
FDA	Food and Drug Administration
FFE	Federally-facilitated Exchange
FF–SHOP	Federally-facilitated Small Business Health Options Program
FPL	Federal poverty level
FR	Federal Register
FTE	Full-time equivalent
HCC	Hierarchical condition category
HDHP	High deductible health plan
HHS	United States Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
HMO	Health maintenance organization
IRS	Internal Revenue Service
LEP	Limited English proficient/proficiency
MLR	Medical loss ratio
NAIC	National Association of Insurance Commissioners
NDC	National Drug Code
NHEA	National Health Expenditure Accounts
OMB	Office of Management and Budget
PCIP	Pre-Existing Condition Insurance Plan
PHS Act	Public Health Service Act
PI	Personal income
PMPM	Per member per month
PPO	Preferred provider organization
QHP	Qualified health plan
QIA	Quality improvement activities
RXC	Prescription Drug Categories
SADP	Stand-alone dental plan
SBC	Summary of benefits and coverage
SBE–FP	State-based Exchange on the Federal platform
SHOP	Small Business Health Options Program
The Code	Internal Revenue Code of 1986 (26 U.S.C. 1, *et seq.*)
USP	United States Pharmacopeia

I. Executive Summary

The Affordable Care Act enacted a set of reforms that are making high quality health insurance coverage and care more affordable and accessible to millions of Americans. These reforms include the creation of competitive marketplaces called Affordable Insurance Exchanges, or "Exchanges" (in this proposed rule, we also call an Exchange a Health Insurance Marketplace^{SM},[1] or Marketplace^{SM}), through which qualified individuals and qualified employers can purchase health insurance coverage. In addition, many individuals who enroll in qualified health plans (QHPs) through individual market Exchanges are eligible to claim a premium tax credit to make health insurance premiums more affordable, and reductions in cost-sharing payments to reduce out-of-pocket expenses for health care services. These Affordable Care Act reforms also include the risk adjustment program and rules that are intended to mitigate the potential impact of adverse selection and stabilize the price of health insurance in the individual and small group markets. In previous rulemaking, we have outlined the major provisions and parameters related to many Affordable Care Act programs.

In this proposed rule, to further promote stable premiums in the individual and small group markets, we propose several updates to the risk adjustment methodology based on our experience with the program to date that are intended to refine the methodology's ability to estimate risk. In particular, we propose updates to better estimate the risk associated with enrollees who are not enrolled for a full 12 months, to use prescription drug data to update the predictive ability of our risk adjustment models, and to establish transfers that will better account for the risk of high-cost enrollees. We propose a number of policies relating to the use of external data gathering environment (EDGE) server data for recalibration of our risk adjustment models, and the use of more recent data for future calibrations. We also propose several amendments to the risk adjustment data validation process, including proposals relating to the review of prescription drug data and the establishment of a discrepancy identification and administrative appeals process.

In addition to provisions aimed at stabilizing premiums, we propose several provisions related to cost-sharing parameters. First, we propose the premium adjustment percentage for 2018, which is used to set the rate of increase for several parameters detailed in the Affordable Care Act, including the maximum annual limitation on cost sharing for 2018. We also propose the maximum annual limitations on cost sharing for the 2018 benefit year for cost-sharing reduction plan variations. This proposed rule also proposes standards for stand-alone dental plans (SADPs) related to the annual limitation on cost sharing.

We also propose a number of amendments that we believe would help promote consumer choice in health plans. These include a proposal specifying that at least one QHP in the silver coverage level and at least one QHP in the gold coverage level must be offered throughout each service area in which a QHP issuer offers coverage through the Exchange; and a proposal to permit a broader de minimis range for the actuarial value of bronze plans to permit greater flexibility in benefit design and to accommodate proposed updates to the 2018 Actuarial Value (AV) Calculator.

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[1] Health Insurance Marketplace^{SM} and Marketplace^{SM} are service marks of the U.S. Department of Health & Human Services.

Our proposal requiring QHP issuers on an Exchange to participate in the Exchange for a full plan year (unless a basis for suppression applies) as a QHP certification requirement would help ensure that individuals enrolling through special enrollment periods and newly qualified employees have access to a range of plans that is generally comparable to the range of plans that can be accessed by those who enroll during an open enrollment period. We also seek comment on whether to remove a requirement tying participation in the individual market Federally-facilitated Exchanges to participation in the Federally-facilitated Small Business Health Options Programs.

We also propose to expand the medical loss ratio (MLR) provision allowing issuers to defer reporting of policies newly issued with a full 12 months of experience (rather than policies newly issued and with less than 12 months of experience) in that MLR reporting year, and to limit the total rebate liability payable with respect to a given calendar year. We propose several changes to our guaranteed renewability regulations that would address instances where issuers may inadvertently trigger a 5-year prohibition on re-entering an applicable market. In these select instances, we believe it is appropriate to allow issuers to remain in the applicable market, and believe allowing so will improve the availability of choice for consumers. We also propose a change to our age rating rules for children.

In this proposed rule, we propose several provisions regarding when and how consumers may choose and enroll in plans. This rule includes proposals relating to codifying several special enrollment periods that are already available to consumers in order to ensure the rules are clear and to limit abuse; the enrollment processes in the Small Business Health Options Program (SHOP); and binder payment deadlines. We also propose several amendments related to insurance affordability programs, including regarding eligibility determinations, and periodic data matching.

We are proposing a number of amendments to assist consumers in selecting and enrolling in QHPs and insurance affordability programs. In the HHS Notice of Benefit and Payment Parameters for 2017 Final Rule (2017 Payment Notice), we established standardized options, which we will display on *HealthCare.gov* in a manner that distinguishes them from other QHPs, and a categorization of network depth. We believe both policies will make it easier for consumers to select health plans through *HealthCare.gov*. In this proposed rule, we expand upon both policies. For standardized options, we propose four bronze standardized options (including one health savings account-eligible high deductible health plan), and three standardized options at each of the silver, silver cost-sharing reduction variations, and gold metal levels. We propose to select one standardized option at each metal level and one at each cost-sharing reduction plan variation level for use in each State. We hope that by increasing the scope of potential standardized designs, we will better accommodate State cost-sharing laws. We also propose to make differential display of standardized options available in State-based Exchanges on the Federal platform (SBE–FPs) at the State's option, as well as to require differential display of standardized options by QHP issuers and web-brokers using a direct enrollment pathway to facilitate enrollment through a Federally-facilitated Exchange (FFE) or SBE–FP. Additionally, we propose a number of standards and consumer protections that would apply to a web-broker or issuer using the direct enrollment pathway. We propose to augment our network adequacy display policy to account for QHPs that are part of an integrated delivery system. We also make proposals relating to the essential community provider requirements and propose amendments to the standards regarding providing taglines in non-English languages indicating the availability of language services.

We seek comment on potential ways to further support the transition of former Pre-Existing Condition Insurance Plan (PCIP) Program enrollees into the Exchange to ensure that they do not experience a lapse in coverage.

We also propose several amendments that would strengthen Exchanges' oversight capabilities. These include proposals requiring issuers attempting to rescind coverage purchased through the Exchange to show that the rescission is appropriate; and making explicit HHS's authority to impose civil money penalties (CMPs) in situations where QHP issuers are non-responsive or uncooperative with compliance reviews. We also propose an avenue through which issuers can appeal a non-certification or decertification.

Finally, in this proposed rule, we propose minor adjustments to our rules governing the single risk pool, SHOP, user fees, and notices, including notices related to SHOP, decertification, and appeals.

II. Background

A. Legislative and Regulatory Overview

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this proposed rule, we refer to the two statutes collectively as the "Affordable Care Act."

The Affordable Care Act reorganizes, amends, and adds to the provisions of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.

Section 2701 of the PHS Act, as added by the Affordable Care Act, restricts the variation in premium rates charged by a health insurance issuer for non-grandfathered health insurance coverage in the individual or small group market to certain specified factors. The factors are: Family size, geographic area, age, and tobacco use.

Section 2701 of the PHS Act operates in coordination with section 1312(c) of the Affordable Care Act. Section 1312(c) of the Affordable Care Act generally requires a health insurance issuer to consider all enrollees in all health plans (except grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. States have the option to merge the individual and small group market risk pools under section 1312(c)(3) of the Affordable Care Act.

Section 2702 of the PHS Act, as added by the Affordable Care Act, requires health insurance issuers that offer health insurance coverage in the group or individual market in a State to offer coverage to and accept every employer and individual in the State that applies for such coverage, unless an exception applies.[2]

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[2] Before enactment of the Affordable Care Act, the Health Insurance Portability and Accountability Act of 1996 amended the PHS Act (formerly section

Section 2703 of the PHS Act, as added by the Affordable Care Act, and former section 2712 and section 2742 of the PHS Act, as added by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), require health insurance issuers that offer health insurance coverage in the group or individual market to renew or continue in force such coverage at the option of the plan sponsor or individual unless an exception applies.

Section 2718 of the PHS Act, as added by the Affordable Care Act, generally requires health insurance issuers to submit an annual medical loss ratio report to HHS, and provide rebates to enrollees if the issuers do not achieve specified MLR thresholds.

Section 2794 of the PHS Act, as added by the Affordable Care Act, directs the Secretary of HHS (the Secretary), in conjunction with the States, to establish a process for the annual review of unreasonable increases in premiums for health insurance coverage.[3] The law also requires health insurance issuers to submit to the Secretary and the applicable State justifications for unreasonable premium increases prior to the implementation of the increases. Section 2794(b)(2) of the PHS Act further directs the Secretary, in conjunction with the States, to monitor premium increases of health insurance coverage offered through an Exchange or outside of an Exchange beginning with plan years starting in 2014.

Section 1101 of the Affordable Care Act required the Secretary to establish a temporary high-risk health insurance pool program to provide health insurance coverage from the establishment of the program until January 1, 2014 for eligible individuals, namely U.S. residents who are U.S. citizens or lawfully present in the U.S.; did not have other health insurance coverage in the 6 months preceding enactment; and have a pre-existing condition. Section 1101 also requires that the Secretary develop procedures to provide for the transition of eligible individuals enrolled in this health insurance coverage into qualified health plans offered through an Exchange to avoid a lapse in coverage.

Section 1302 of the Affordable Care Act provides for the establishment of an essential health benefits (EHB) package that includes coverage of EHB (as defined by the Secretary), cost-sharing limits, and actuarial value (AV) requirements. The law directs that EHBs be equal in scope to the benefits covered by a typical employer plan and that they cover at least the following 10 general categories: Ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

Section 1301(a)(1)(B) of the Affordable Care Act directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the Affordable Care Act, including coverage of the services described in section 1302(b) of the Affordable Care Act, to adhere to the cost-sharing limits described in section 1302(c) of the Affordable Care Act and to meet the AV levels established in section 1302(d) of the Affordable Care Act. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or after January 1, 2014, extends the coverage of the EHB package to non-grandfathered individual and small group market coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost sharing under the plan does not exceed the limitations described in section 1302(c)(1) of the Affordable Care Act.

Section 1302(d) of the Affordable Care Act describes the various levels of coverage based on actuarial value. Consistent with section 1302(d)(2)(A) of the Affordable Care Act, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the Affordable Care Act directs the Secretary to develop guidelines that allow for de minimis variation in AV calculations.

Section 1311(b)(1)(B) of the Affordable Care Act directs that the Small Business Health Options Program assist qualified small employers in facilitating the enrollment of their employees in qualified health plans offered in the small group market. Sections 1312(f)(1) and (2) of the Affordable Care Act define qualified individuals and qualified employers. Under section 1312(f)(2)(B) of the Affordable Care Act, beginning in 2017, States will have the option to allow issuers to offer QHPs in the large group market through an Exchange.[4]

Section 1311(c)(1)(B) of the Affordable Care Act requires the Secretary to establish minimum criteria for provider network adequacy that a health plan must meet to be certified as a QHP.

Section 1311(c)(5) of the Affordable Care Act requires the Secretary to continue to operate, maintain, and update the Internet portal developed under section 1103 of the Affordable Care Act to provide information to consumers and small businesses on affordable health insurance coverage options.

Section 1311(c)(6)(C) of the Affordable Care Act states that the Secretary is to provide for special enrollment periods specified in section 9801 of the Internal Revenue Code of 1986 (the Code) and other special enrollment periods under circumstances similar to such periods under part D of title XVIII of the Social Security Act (the Act).

Section 1312(e) of the Affordable Care Act directs the Secretary to establish procedures under which a State may permit agents and brokers to enroll qualified individuals and qualified employers in QHPs through an Exchange, and to assist individuals in applying for financial assistance for QHPs sold through an Exchange.

Section 1321(a) of the Affordable Care Act provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the Affordable Care Act. Section 1321(a)(1) directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the Affordable Care Act with respect to, among other things, the establishment and operation of Exchanges.

Sections 1313 and 1321 of the Affordable Care Act provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1321 of the Affordable Care Act provides for State flexibility in the operation and enforcement of Exchanges and related requirements.

When operating a Federally-facilitated Exchange under section 1321(c)(1) of the Affordable Care Act, HHS has the

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2711) to generally require guaranteed availability of coverage for employers in the small group market.

[3] The implementing regulations in part 154 limit the scope of the requirements under section 2794 of the PHS Act to health insurance issuers offering health insurance coverage in the individual market or small group market.

[4] If a State elects this option, the rating rules in section 2701 of the PHS Act and its implementing regulations will apply to all coverage offered in such State's large group market under section 2701(a)(5) of the PHS Act.

authority under sections 1321(c)(1) and 1311(d)(5)(A) of the Affordable Care Act to collect and spend user fees. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Office of Management and Budget (OMB) Circular A–25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. Furthermore, these user fees are appropriated to CMS in the CMS Program Management appropriation.

Section 1321(c)(2) of the Affordable Care Act authorizes the Secretary to enforce the Exchange standards using CMPs on the same basis as detailed in section 2723(b) of the PHS Act. Section 2723(b) of the PHS Act authorizes the Secretary to impose CMPs as a means of enforcing the individual and group market reforms contained in part A of title XXVII of the PHS Act with respect to health insurance issuers when a State fails to substantially enforce these provisions.

Section 1321(d) of the Affordable Care Act provides that nothing in title I of the Affordable Care Act should be construed to preempt any State law that does not prevent the application of title I of the Affordable Care Act. Section 1311(k) of the Affordable Care Act specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1343 of the Affordable Care Act establishes a risk adjustment program in which States, or HHS on behalf of States, collects charges from health insurance issuers that attract lower-risk populations in order to use those funds to provide payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, thereby reducing incentives for issuers to avoid higher-risk enrollees.

Sections 1402 and 1412 of the Affordable Care Act provide for, among other things, reductions in cost sharing for essential health benefits for qualified low- and moderate-income enrollees in silver level health plans offered through the individual market Exchanges. These sections also provide for reductions in cost sharing for Indians enrolled in QHPs at any metal level.

1. Premium Stabilization Programs

In the July 15, 2011 **Federal Register** (76 FR 41929), we published a proposed rule outlining the framework for the premium stabilization programs. We implemented the premium stabilization programs in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73117), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs (proposed 2014 Payment Notice). We published the 2014 Payment Notice final rule in the March 11, 2013 **Federal Register** (78 FR 15409).

In the December 2, 2013 **Federal Register** (78 FR 72321), we published a proposed rule outlining the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2015 Payment Notice). We published the 2015 Payment Notice final rule in the March 11, 2014 **Federal Register** (79 FR 13743).

In the November 26, 2014 **Federal Register** (79 FR 70673), we published a proposed rule outlining the benefit and payment parameters for the 2016 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2016 Payment Notice). We published the 2016 Payment Notice final rule in the February 27, 2015 **Federal Register** (80 FR 10749).

In the December 2, 2015 **Federal Register** (80 FR 75487), we published a proposed rule outlining the benefit and payment parameters for the 2017 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2017 Payment Notice). We published the 2017 Payment Notice final rule in the March 8, 2016 **Federal Register** (81 FR 12203).

2. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37031), we published a proposed rule that proposed certain program integrity standards related to Exchanges and the premium stabilization programs (proposed Program Integrity Rule). The provisions of that proposed rule were finalized in two rules, the "first Program Integrity Rule" published in the August 30, 2013 **Federal Register** (78 FR 54069) and the "second Program Integrity Rule" published in the October 30, 2013 **Federal Register** (78 FR 65045).

3. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to States on Exchanges on November 18, 2010. We proposed a rule in the July 15, 2011 **Federal Register** (76 FR 41865) to implement components of the Exchanges, and a rule in the August 17, 2011 **Federal Register** (76 FR 51201) regarding Exchange functions in the individual market, eligibility determinations, and Exchange standards for employers. A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges was published in the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule).

We established standards for SHOP in the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541). We also set forth standards related to Exchange user fees in the 2014 Payment Notice.

In the 2017 Payment Notice we established additional Exchange standards, including requirements for State Exchanges using the Federal platform and standardized options.

In an interim final rule with comment published in the May 11, 2016 **Federal Register** (81 FR 29146) we amended the parameters of certain special enrollment periods.

4. Essential Health Benefits and Actuarial Value

On December 16, 2011, HHS released a bulletin[5] (the EHB Bulletin) that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. HHS also published a bulletin that outlined its intended regulatory approach to calculations of AV on February 24, 2012.[6] A proposed rule relating to EHBs and AVs was published in the November 26, 2012 **Federal Register** (77 FR 70643). We established requirements relating to EHBs and AVs in the Standards Related to Essential Health Benefits, Actuarial Value, and

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[5] Essential Health Benefits Bulletin. (Dec. 16, 2011). Available at: *https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.*

[6] Actuarial Value and Cost-Sharing Reductions Bulletin. Feb. 24, 2012. Available at: *https://www.cms.gov/CCIIO/Resources/Files/Downloads/Av-csr-bulletin.pdf.*

Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12833) (EHB Rule).

5. Market Rules

A proposed rule relating to the 2014 health insurance market rules was published in the November 26, 2012 **Federal Register** (77 FR 70584). A final rule implementing the health insurance market rules was published in the February 27, 2013 **Federal Register** (78 FR 13406) (2014 Market Rules).

A proposed rule relating to Exchanges and Insurance Market Standards for 2015 and Beyond was published in the March 21, 2014 **Federal Register** (79 FR 15808) (2015 Market Standards Proposed Rule). A final rule implementing the Exchange and Insurance Market Standards for 2015 and Beyond was published in the May 27, 2014 **Federal Register** (79 FR 30240) (2015 Market Standards Rule).

6. Rate Review

A proposed rule to establish the rate review program was published in the December 23, 2010 **Federal Register** (75 FR 81003). A final rule with comment period implementing the rate review program was published in the May 23, 2011 **Federal Register** (76 FR 29963) (Rate Review Rule). The provisions of the Rate Review Rule were amended in final rules published in the September 6, 2011 **Federal Register** (76 FR 54969), the February 27, 2013 **Federal Register** (78 FR 13405), the May 27, 2014 **Federal Register** (79 FR 30339), and the February 27, 2015 **Federal Register** (80 FR 10749).

7. Medical Loss Ratio

We published a request for comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297), and published an interim final rule relating to the MLR program on December 1, 2010 (75 FR 74863). A final rule was published in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule was published in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was published in the **Federal Register** on May 16, 2012 (77 FR 28790).

8. Pre-Existing Condition Insurance Plan Program

We published an interim final rule in the July 30, 2010 **Federal Register** (75 FR 45013) setting forth implementing regulations for the Pre-Existing Condition Insurance Plan Program. An amendment to this interim final rule was published in the August 30, 2012 **Federal Register** (77 FR 52614). We published an interim final rule in the May 22, 2013 **Federal Register** (78 FR 30218).

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the operation of Exchanges, including the SHOPs, and the premium stabilization programs. We have held a number of listening sessions with consumers, providers, employers, health plans, the actuarial community, and State representatives to gather public input. We consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with States through the Exchange Establishment grant and Exchange Blueprint approval processes, and meetings with Tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties.

On March 31, 2016, we hosted a public conference to discuss the potential improvements to the Federally certified HHS-operated risk adjustment methodology. Prior to the conference, we published the "March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting: Discussion Paper" ("White Paper"),[7] on which we received public comment. These comments are available at: *https://www.regtap.info/uploads/library/RA_Onsite_Discussion_Paper_Comments_5CR_080916.pdf.*

We considered all public input we received as we developed the policies in this proposed rule.

C. Structure of Proposed Rule

The regulations outlined in this proposed rule would be codified in 45 CFR parts 144, 146, 147, 148, 153, 154, 155, 156, 157 and 158.

The proposed regulations in parts 144 and 154 would make conforming revisions to the regulatory definitions of "plan" and "product."

The proposed regulations in parts 146, 147 and 148 would address two scenarios in which the discontinuation of all coverage currently offered by an issuer within a market and State will not be treated as a market withdrawal for purposes of the guaranteed renewability requirements. The proposed regulations in part 147 would also create multiple child age bands for rating purposes, and would amend the provision regarding limited open enrollment periods (also known as special enrollment periods) in the individual market to reflect the proposed amendments regarding special enrollment periods in the Exchanges.

The discussion in part 152 seeks comment on potential approaches to ensure the successful transition of former Pre-Existing Condition Insurance Plan (PCIP) Program enrollees to the Exchange without a lapse in coverage, under the PCIP statute.

The proposed regulations in part 153 include the risk adjustment user fee for 2018 and outline a number of proposed modifications to the HHS risk adjustment methodology, including modifications to: (1) Address partial year enrollment; (2) use prescription drug data to predict actuarial risk; and (3) alter the methodology to better account for high-cost enrollees. We also propose to use EDGE server data to recalibrate the risk adjustment models, and propose revisions to the risk adjustment data validation process.

The proposed regulations in part 155 include several amendments regarding standardized options, including the 2018 cost-sharing structures for standardized options. Other proposals in part 155 are related to the eligibility and verification processes for insurance affordability programs. We propose to amend rules related to enrollment of qualified individuals into QHPs and make various proposals related to the SHOPs. We propose to amend the regulations requiring Exchanges, QHP issuers, and web-brokers to provide taglines in non-English languages. We propose the required contribution percentage for 2018. We propose a new policy regarding appealing denials of QHP certification. We also propose amendments to the standards applicable in State Exchanges using the Federal platform for SHOP functions in parts 155 and 156. We also propose amendments to the regulations applicable to qualified employers in the SHOPs in part 157.

The proposed regulations in part 156 set forth proposals related to cost-sharing parameters, including the premium adjustment percentage, the maximum annual limitation on cost sharing, and the reductions in the maximum annual limitation for cost-sharing plan variations for 2018. We also propose the user fee rate applicable in the FFEs and SBE–FPs. The proposed regulations also include an amendment providing for calibration of the single risk pool index rate. We also propose changes regarding AV, levels of coverage, and essential community provider requirements.

The proposed amendments to the regulations in part 158 propose revisions related to deferral of reporting of experience for newer business, as well as revisions related to limiting the total rebate liability payable with respect to a given calendar year.

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[7] Available at: *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.*

III. Provisions of the Proposed HHS Notice of Benefit and Payment Parameters for 2018

A. Part 144—Requirements Relating to Health Insurance Coverage

1. Definitions (§ 144.103)

We propose to revise the regulatory definitions of "plan" and "product" in § 144.103. Specifically, we propose to remove language from each definition that would restrict a plan or product from being considered the same plan or product when it is no longer offered by the same issuer, but is still offered by a different issuer in the same controlled group. We also propose to add a second sentence to clarify that, in the case of a product that has been modified, transferred, or replaced, the product will be considered to be the same product when it meets the standards for uniform modification of coverage at § 146.152(f), § 147.106(e), or § 148.122(g), as applicable. For further discussion of the provisions of this proposed rule related to the transfer or replacement of all products in a market in a State, please see the preamble to § 147.106. Finally, for purposes of clarity, we propose to include examples of product network types in the definition of "product" in § 144.103, including health maintenance organization (HMO), preferred provider organization (PPO), exclusive provider organization, point of service, and indemnity.

B. Part 146—Requirements for the Group Health Insurance Market

1. Guaranteed Renewability of Coverage for Employers in the Group Market (§ 146.152)

For a discussion of the provisions of this proposed rule related to part 146, please see the preamble to § 147.106.

C. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Fair Health Insurance Premiums (§ 147.102)

Section 2701 of the PHS Act, as implemented at 45 CFR 147.102(a)(3), permits premium rates to vary based on age within a ratio of 3 to 1 for adults. Section 147.102(d) provides for uniform age bands, including a single age band for individuals age 0 through 20. In the proposed 2017 Payment Notice (80 FR 75496), we stated that we recognized that the Federal child age band and factor may need to be updated to better reflect the health risk of children. While average health care costs vary by the age of the child, in general, claim costs are highest for children age 0 through 4, followed by individuals age 15 through 20. Children age 5 through 14 generally have lower claim costs. Having one age band for individuals age 0 through 20, together with the current child age factor, may result in significant premium increases for an individual when reaching age 21. In general, the premium at age 21 is 57% higher than the premium at age 20. Therefore, we sought comment regarding age rating for children to inform our reconsideration of the child age rating factor in the Federal uniform age curve.[8]

Most comments submitted to HHS in response to the proposed 2017 Payment Notice supported continuing to spread the cost of newborns across a broader age band, and supported a more gradual transition in premiums up to age 21. Some stakeholders also indicated that the default child age factor of 0.635 should be higher, stating that the relatively low child age factor currently leads to insufficient premiums for children. We conducted an analysis of total annual cost from a national commercial database that incorporates 2015 claims data from the individual and small group markets. Based on this analysis, we propose to amend § 147.102(d) to create multiple child age bands and propose a corresponding increase in the overall child age factor.

We propose one age band for individuals age 0 through 14 and then single-year age bands for individuals age 15 through 20, effective for plan years or policy years beginning on or after January 1, 2018. Establishing single-year age bands beginning at age 15 would be likely to result in small annual increases in premiums for children age 15 to 20, which would help mitigate large premium increases attributable to age due to the transition from a child to an adult age rating. However, we solicit comments on alternative approaches that would achieve these objectives.

We recognize that age rating factors have a significant impact on issuers' approach to developing health insurance rates and therefore also propose age rating factors for the default Federal standard child age curve. These factors, listed in Table 1, correspond to the proposed change to child age bands. We solicit comments on these child age rating factors and whether they should be implemented at one time or phased in over a 3-year period. As stated in the preamble to the 2014 Market Rules (78 FR at 13413), we intend to revise the default Federal standard age curve periodically in guidance, but no more frequently than annually, to reflect market patterns in the individual and small group markets. We propose to reflect this approach by amending § 147.102(e). We intend to monitor the effect of these new age bands and rating factors, if finalized, to determine whether further refinements are needed.

TABLE 1—CMS STANDARD AGE CURVE FOR CHILDREN

Age	Current premium ratio	Proposed premium ratio
0–14	0.635	0.765
15	0.635	0.833
16	0.635	0.859
17	0.635	0.885
18	0.635	0.913
19	0.635	0.941
20	0.635	0.970

2. Guaranteed Availability of Coverage (§ 147.104)

For a discussion of the provisions of this proposed rule related to limited open enrollment periods (also known as special enrollment periods) in § 147.104, please see the preamble to § 155.420.

The guaranteed availability requirement in section 2702 of the PHS Act generally requires each health insurance issuer that offers health insurance coverage in the group or individual market in a State to accept every employer or individual in the State that applies for such coverage. However, in the case of an issuer that offers coverage through a network plan, the issuer may limit its offer of coverage to individuals in the individual market who live or reside in the service area of such network plan, and to employers in the small group or large group market with employees who live, work, or reside in the service area of such network plan.[9]

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[8] Under 45 CFR 147.102(e), each State may establish a uniform age rating curve in the individual or small group market, or both markets, for rating purposes. If a State does not establish a uniform age rating curve or provide information on such age curve in accordance with § 147.103, a default uniform age rating curve specified in guidance by the Secretary will apply in that State that takes into account the rating variation permitted for age under State law.

[9] In the 2014 Market Rules, we codified in regulation the ability of an issuer of a network plan to limit the availability to individuals who live or reside in the service area, noting that "[w]hile PHS Act section 2702(c)(1)(A) does not explicitly include a corresponding exception allowing issuers to limit the sale of individual market coverage to individuals who live or reside in the individual market plan's service area, failing to recognize such an exception would eliminate an issuer's ability to

This protection under Federal law does not require that the employer have a principal business address within the issuer's service area.[10] In the 2017 Payment Notice, we amended § 147.102 to ensure that a network plan could be appropriately rated for sale to an employer with employees in multiple geographical rating areas, consistent with both the rating rules and the guaranteed availability requirements.

We understand that some issuers have unique network sharing agreements with other affiliated issuers through which an employer's employees may access in-network coverage outside the service area of the primary issuer, using the provider network of the affiliated issuers. Under the terms of these agreements, the affiliated issuers require the employer itself to be located in the issuer's service area in order to be eligible to purchase coverage, and the issuers agree not to offer products to an employer whose business headquarters is outside of the primary issuer's service area. For example, affiliated issuers A and B have service areas A and B, respectively. Under the terms of the agreements, an employer with business headquarters in service area A could purchase coverage from issuer A to cover its employees in both service areas A and B, but that employer could not purchase coverage from issuer B.

We understand these issuers believe issuer B satisfies the guaranteed availability requirements because the employer is guaranteed coverage from issuer A, and its employees in service area B can have access to the coverage under the plan issued by issuer A using issuer B's network. These issuers explain that this system promotes simplicity for employers, who can purchase a single plan from one of the locally affiliated issuers serving the employer's area to cover their employees in multiple service areas.

We seek comment on whether and how restricting an employer's ability to purchase coverage from an issuer, when the offering of such coverage would not exceed the scope of the issuer's license from the applicable State authority, may limit employers' options.

We also seek comments on these and other similar arrangements and whether or how they could be structured, consistent with State licensure requirements, to satisfy the guaranteed availability right of employers to purchase all products that are approved for sale from an issuer when the employer has employees who live, work, or reside within the issuer's service area.

3. Guaranteed Renewability of Coverage (§ 147.106)

a. Market Withdrawal Exception to Guaranteed Renewability Requirements

PHS Act section 2703(c)(2)(B) provides that a health insurance issuer that elects to discontinue all health insurance coverage in the individual or group market in a State is prohibited from re-entering the applicable market for at least 5 years. The 5-year ban on market re-entry is codified at § 147.106(d)(2). However, we recognize that interpreting certain issuer transactions or reorganizations to be withdrawals from the market, triggering the 5-year ban on market re-entry, may have unintended effects and may not be necessary to ensure the continuity of coverage for consumers, which is a primary focus of the protections in the guaranteed renewability statute.

For example, as part of a corporate reorganization, an issuer could transfer all of its products to another related issuer, where the products otherwise would be considered the same products based on the uniform modification standards at § 147.106(e). More specifically, an issuer with multiple lines of business, such as a Medicaid managed care line and a commercial line, could decide to create a subsidiary and transfer its commercial line of business to the subsidiary. In such cases, enrollees in the commercial products maintain continuity of coverage when their plans and products are not changed beyond what is permitted by the scope of the uniform modification provisions. We also note that several States evaluate transactions at the holding company level and have informed HHS that a transaction of the type described in this example would not trigger the 5-year ban on market re-entry and corresponding notice requirement under State law.

We recognize that interpreting such a transfer to constitute a market withdrawal could have the unintended consequences of potentially raising conflicts with State approaches and unnecessarily limiting issuer corporate structuring transactions. Therefore, to align with State approaches to corporate structuring or other transactions within a controlled group of issuers, and to avoid unintended market bans where continuity of coverage is effectively provided, we propose to amend § 147.106(e)(3)(i) to provide that, for purposes of guaranteed renewability, a product will be considered to be the same product when offered by a different issuer within an issuer's controlled group, provided it otherwise meets the standards for uniform modification of coverage.[11]

For this purpose, we propose to use a definition based on the Internal Revenue Service (IRS) definition of controlled group that applies for purposes of determining whether a group of two or more persons is treated as a single covered entity under the health insurance providers fee under section 9010 of the Affordable Care Act and 26 CFR 57.2(c). Specifically, for purposes of guaranteed renewability, we propose that "controlled group" means a group of two or more persons that is treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended. We propose that definition for consistency with other Affordable Care Act provisions, including sections 9008 and 9010, which pertain to the branded prescription drug fee and health insurance providers fee, respectively, and are familiar to health insurance issuers. We note that the definition of issuer group under 45 CFR 156.20 is also familiar to issuers and we are considering whether to use a similar definition for purposes of these regulations. That section provides that the term issuer group means all entities treated under subsection (a) or (b) of section 52 of the Code as a member of the same controlled group of corporations as (or under common control with) a health insurance issuer, or issuers affiliated by the common use of a nationally licensed service mark. We solicit comment on whether this or another definition would be appropriate.

As a result of this proposal, issuers transferring products to another issuer in their controlled group that otherwise remain within the scope of a uniform modification would not be required to

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define a service area for its individual market business within a State. Moreover, references to persons with individual market coverage in paragraph (c)(1) and subparagraph (c)(1)(B) of PHS Act section 2702 suggest that such persons with individual market coverage also were intended to be described in paragraph (c)(1)(A)."

[10] However, this provision does not require an issuer to offer coverage to an employer whose place of business is located outside the State in which the issuer is licensed to do business. Further, this provision does not require an issuer to offer coverage to an employer if doing so would exceed the scope of the issuer's State licensure (for example, the issuer's product is not approved for sale to an employer where the situs of the contract is outside the issuer's service area).

[11] As we explained in an FAQ related to Market Reforms, *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/qa_hmr.html*, enrollees in a grandfathered product can maintain that coverage if that coverage continues to be offered and the coverage does not make a change that would cause the product to cease to be grandfathered as provided for in regulations. See 26 CFR 54.9815–1251(g)(1); 29 CFR 2590.715–1251(g)(1); and 45 CFR 147.140(g)(1).

send discontinuation notices under paragraph (c)(1) or (d)(1), as applicable. However, because this interpretation considers the transferred product to be the same as the product previously offered, the issuer of the coverage at the time notice must be provided (whether the current issuer or the acquiring issuer) would be required to provide a renewal notice in accordance with the timeframe specified in the regulation. We also propose that States that interpret or apply market withdrawal provisions differently under State law would not be prohibited by this interpretation from considering products transferred to a different issuer within a controlled group to be a new product and the scenario a market withdrawal. We propose to make conforming amendments at §§ 146.152(f)(3)(i) and 148.122(g)(3)(i). Because, under this interpretation, the products would be considered the same products for purposes of continuity of coverage for the enrollees, we also propose that the products be considered the same products for purposes of the Federal rate review requirements, to the extent applicable, and therefore we propose conforming amendments as described in the preamble to § 154.102. For States where HHS is responsible for enforcement of the guaranteed renewability provisions of the PHS Act, we propose to adopt this interpretation and not consider the transfer of products to a different issuer within a controlled group to be a market withdrawal when the conditions in this proposed rule are met, where permitted under applicable State law.

There is a second situation where we have determined that it may not be appropriate to interpret an issuer's actions to constitute a market withdrawal resulting in a 5-year ban on market re-entry. When an issuer discontinues offering all of its products and seeks to offer new products within the same market, if the changes made to the new products exceed the scope of a uniform modification of coverage, we have considered such an action to be a market withdrawal, subject to the 5-year ban on market re-entry.[12] In such a scenario an issuer might, for example, offer only products A, B, and C one year, but then offer only products D, E, and F the next year, where products D, E and F differ from products A, B and C in ways that do not meet the criteria for uniform modification of coverage. This scenario is different from the first scenario mentioned above because the new products are offered by the same issuer that previously offered the discontinued products. State regulators and other interested parties have indicated that this scenario is not viewed by some States as a market withdrawal under State law, as long as the issuer continues to provide a product in the same market in which it previously offered the discontinued products.[13] As noted above, we believe ensuring continuity of coverage for consumers is a primary focus of the protections in the guaranteed renewability statute. Unlike the circumstances described in the prior scenario, where the enrollee has continuity of the product, but with a related issuer, in the situation described here, enrollees would have continuity with the same issuer, but would not have the protection of the limitations imposed by the uniform modification provision. Notwithstanding our prior interpretation described in the Uniform Modification and Plan/Product Withdrawal FAQ,[14] we recognize that the statute could be interpreted to mean that, as long as an issuer has a product available in the applicable market (even if that issuer discontinues all of its previously offered products), it has not withdrawn from the applicable market. Adopting this interpretation may be in the best interest of consumers, as imposing the 5-year ban on market re-entry in these circumstances could diminish consumer choice and market competition.

We note that, under our current interpretation requiring that the issuer leave at least one product in place that meets uniform modification standards to avoid the 5-year market ban on re-entry, the issuer would remain subject to Federal rate review under section 2794 with respect to at least one product. Under the new interpretation, an issuer would be able to avoid Federal rate review altogether without triggering the 5-year ban by sufficiently altering all of its existing products. To prevent issuers from avoiding Federal rate review requirements in this manner, we propose to permit issuers to replace their entire portfolio of products without triggering the 5-year ban under the market withdrawal provision when an issuer replaces its entire portfolio of products in a market with products that are different in ways that are not within the scope of uniform modifications, provided the issuer reasonably identifies which newly offered product (or products) replace which discontinued product (or products) and subjects the new product (or products) to the Federal rate review process under part 154 (to the extent otherwise applicable to coverage of the same type and in the same market (for example, the Federal rate review process does not apply in the U.S. territories)) as if it were the same product as the discontinued product it replaces.[15] An issuer's identification of which new product replaces which discontinued product would be considered reasonable if it reflects the issuer's expectations regarding significant transfer of enrollment from one product to the other (for example, because the products have been cross-walked for auto-reenrollment). We also propose that States that interpret or apply market withdrawal provisions differently under State law would not be prohibited from continuing to consider the scenario described here as a market withdrawal. For States where HHS is responsible for enforcement of the guaranteed renewability provisions of the PHS Act, we propose to adopt this interpretation and not consider this scenario to constitute a market withdrawal when the conditions outlined in this proposed rule are met, where permitted under applicable State law.

We note that in the second scenario, consumers generally will still get the protection required under the product discontinuance provision under guaranteed renewability, including a special enrollment period for loss of minimum essential coverage to select another product made available by the same or a different issuer, and a notice from the issuer of the product discontinuance at least 90 days in advance of the termination of coverage.[16]

To reflect our proposed interpretations in these two scenarios, we propose to add a new paragraph (d)(3) to § 147.106 to provide that an issuer has not discontinued offering all health insurance coverage in a market if a member of the issuer's controlled group continues to offer and make available for enrollment at least one product of the original issuer that is considered to be the same product (as proposed to be amended in § 144.103 of this proposed rule), meaning that any change to the product is within the scope of a uniform modification of coverage under § 147.106(e), or if the issuer continues to offer and make available a product in the applicable market in a State and subjects the new product to the rate review requirements under part 154 of this title (to the extent otherwise applicable to coverage of the same type and in the same market) as if that part applied to that product, and reasonably identifies a discontinued product that corresponds to the new product for purposes of such rate review. We also propose to make conforming amendments to §§ 146.152(d)(3) and 148.122(e)(4).

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[12] Uniform Modification and Plan/Product Withdrawal FAQ (Jun. 15, 2015), available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/uniform-mod-and-plan-wd-FAQ-06-15-2015.pdf.*

[13] We also note that, in the context of reenrollment through an Exchange in coverage under a different product, we stated that, under certain limited circumstances, enrollments completed under the hierarchy specified in 45 CFR 155.335(j) will be considered to be a renewal of the enrollee's coverage.

[14] Uniform Modification and Plan/Product Withdrawal FAQ (Jun. 15, 2015). Available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/uniform-mod-and-plan-wd-FAQ-06-15-2015.pdf.*

[15] Under this interpretation, issuers of health insurance products offered in the U.S. territories would be able to replace their products in those markets without subjecting the new products to the Federal rate review process and without triggering the 5-year ban.

[16] As noted earlier, under certain limited circumstances, enrollments through an Exchange into a different product that are completed under the hierarchy specified in 45 CFR 155.335(j) will be considered to be a renewal of the enrollee's coverage. In such cases, a special enrollment period is not available, and a renewal notice is sent.

We solicit comment on all aspects of these proposals.

b. Guaranteed Renewability in the Individual Market and Medicare Eligibility

The guaranteed renewability provision at § 147.106(h)(2) states that Medicare eligibility or entitlement is not a basis for nonrenewal or termination of an individual's health insurance coverage in the individual market. The anti-duplication provision at section 1882(d)(3) of the Act prohibits the sale or issuance of an individual health insurance policy to an individual entitled to benefits under Part A or enrolled under Part B of Medicare[17] with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under Medicare or Medicaid, but does not expressly prohibit the renewal of individual health insurance coverage to someone who becomes entitled to benefits under Part A or enrolls under Part B while enrolled in the individual market coverage. There also is no prohibition on issuers covering Medicare beneficiaries under group health insurance policies.

Under 45 CFR 147.106, in certain circumstances, issuers can satisfy their guaranteed renewability obligations by, at the end of a policy year, reenrolling Medicare beneficiaries who were enrolled in individual market health insurance coverage when they obtained Medicare coverage into a different plan within the same individual health insurance product, or into a different plan within a different individual health insurance product issued by the same issuer of the beneficiary's existing individual market coverage. This may occur, for example, when an issuer makes revisions to a product that exceed the scope of uniform modification of coverage, thus replacing the existing product with a new product. Under our proposal earlier in this section of the preamble, issuers also could satisfy their guaranteed renewability obligations by reenrolling Medicare beneficiaries into individual market health insurance coverage that is considered the same product but that is issued by a different issuer within the issuer's controlled group. We solicit comments on whether the guaranteed renewability statute and the anti-duplication provision at section 1882(d)(3) of the Act should together be interpreted to require or prohibit renewal of a Medicare beneficiary's individual market coverage, if the issuer has knowledge that the renewed coverage would duplicate the Medicare beneficiary's benefits: (1) In a plan under the same contract of insurance; (2) under a plan that was modified but is considered under the guaranteed renewability provisions to be the same plan but that would require a new contract; (3) under a different plan within the same product; (4) under a different product with the same issuer; or, as discussed earlier in this preamble; (5) under the same product offered by a different issuer within the issuer's controlled group. We are particularly interested in information about how requiring or prohibiting renewal in these circumstances could affect individuals' decisions to enroll in the Medicare program, their premiums and out-of-pocket costs if they were insured in the Medicare program versus the individual market, and the effect on Medicare's and the insurance plans' risk pools.

We have become aware of an issue that has arisen with respect to coordination of benefits between Medicare and individual health insurance coverage. Since Medicare Secondary Payer rules do not apply to health coverage in the individual health insurance market, Medicare always pays primary to individual health insurance coverage. Some issuers have a provision in their individual health insurance policies indicating that the coverage will pay secondary to Medicare not only for individuals who are currently covered by Medicare but also for those who could obtain Medicare coverage (such as those individuals who must pay for Part A coverage) but who are not currently covered. We solicit comments on the effects of such provisions on consumers, their premiums, and out-of-pocket costs, how these provisions could affect individuals' decisions to enroll in the Medicare program or individual market coverage, and the effects these provisions and those decisions could have on the Medicare and individual market risk pools, as well as whether this is a permissible coordination of benefits provision with respect to the individuals who could but do not have Medicare coverage. Given that the Medicare Secondary Payer rules have different provisions for End Stage Renal Disease (ESRD) beneficiaries, we also welcome comments on whether a legal basis exists to treat coordination of benefit provisions that relate to coverage in the individual market for Medicare beneficiaries differently for Medicare beneficiaries who are entitled to benefits under Medicare Part A and eligible to enroll under Part B under the ESRD provisions at 42 U.S.C. 426–1.

D. Part 148—Requirements for the Individual Health Insurance Market

1. Guaranteed Renewability of Individual Health Insurance Coverage (§ 148.122)

For a discussion of the provisions of this proposed rule related to part 148, please see the preamble to § 147.106.

E. Part 152—Pre-Existing Condition Insurance Plan Program

1. Pre-Existing Condition Insurance Plan Program (§ 152.45)

Section 1101 of the Affordable Care Act directed HHS to establish a temporary Federal high risk pool program in 2010 to provide health insurance coverage to individuals who were U.S. citizens or nationals or lawfully present in the United States, did not have other health insurance coverage in the 6 months preceding enactment, and had a pre-existing condition. Section 1101(g)(3)(B) directed HHS to develop procedures to provide for the transition of eligible individuals enrolled in health insurance coverage offered through the high risk pool HHS established into qualified health plans offered through an Exchange. Those procedures should, in particular, ensure that there is no lapse in coverage with respect to the individual and may extend coverage after the termination of the risk pool involved, if the Secretary determines necessary to avoid such a lapse.

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[17] For information on when individuals are entitled to, eligible for, or able to enroll in Medicare, see *https://www.cms.gov/medicare/eligibility-and-enrollment/origmedicarepartabeligenrol/index.html.*

Starting in 2010, shortly after the Affordable Care Act was enacted, HHS established and began operating the risk pool program required under section 1101, which it called the Pre-Existing Condition Insurance Plan (PCIP) Program, to provide health insurance coverage to eligible individuals, as defined in the Affordable Care Act. Beginning in 2013, HHS worked to enroll these individuals in QHPs through the Exchanges. However, for a variety of reasons, individuals from the high-risk pool established under section 1101 may find it difficult to obtain and maintain coverage in QHPs without a lapse in coverage.

We are therefore seeking information regarding whether and how the remaining funds provided under section 1101 might be used to ensure the successful transition of former PCIP enrollees to the Exchange without a lapse in coverage, consistent with section 1101(g)(3)(B) and its objective of ensuring that high-risk individuals with preexisting conditions are able to transition successfully into the new Exchanges without a lapse in coverage. We seek information, in particular, on the best ways to identify former PCIP enrollees in a QHP of an issuer that has participated in the Exchange from 2014 to 2017, available methods for determining their claims costs, and the necessity of taking steps to ensure that they do not experience a lapse in coverage. If it is not possible to identify former PCIP enrollees, HHS also seeks information about other appropriate measures to assess the size and impact of former PCIP enrollment on existing issuers.

F. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Under the Affordable Care Act

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2017,[18] both the transitional reinsurance program and risk adjustment program are subject to the fiscal year 2017 sequestration. The Federal government's 2017 fiscal year will begin on October 1, 2016. The reinsurance program will be sequestered at a rate of 6.9 percent for payments made from fiscal year 2017 resources (that is, funds collected during the 2017 fiscal year). To meet the sequestration requirement for the risk adjustment program for fiscal year 2017, HHS will sequester risk adjustment payments made using fiscal year 2017 resources in all States where HHS operates risk adjustment, at a sequestration rate of 7.1 percent. HHS estimates that increasing the sequestration rate for all risk adjustment payments made in fiscal year 2017 to all issuers in the States where HHS operates risk adjustment by 0.16 percent will permit HHS to meet the required national risk adjustment program sequestration percentage of 6.9 percent noted in the OMB Report to Congress.

HHS, in coordination with the OMB, has determined that, under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended, and the underlying authority for these programs, the funds that are sequestered in fiscal year 2017 from the reinsurance and risk adjustment programs will become available for payment to issuers in fiscal year 2018 without further Congressional action. If the Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, these programs would be sequestered in future fiscal years, and any sequestered funding would become available in the fiscal year following that in which it was sequestered.

2. Definition of Large Employer for the Risk Adjustment and Risk Corridors Programs (§ 153.20)

We propose deleting the definition of "large employer" set forth in § 153.20, which defines a large employer as having the meaning given to the term at 45 CFR 155.20.[19] HHS provided notice of our intent to propose these changes in a public FAQ[20] which clarified how an issuer should count an employer's employees to determine whether an employer is a small employer or large employer for purposes of the risk adjustment and risk corridors programs.

In that FAQ, we clarified that for the risk adjustment program, the issuer should use the employee counting method used to determine group size under State law, unless that counting method does not account for employees that are not full-time. If the State counting method does not take non-full-time employees into account, then the issuer should use the counting method under section 4980H(c)(2) of the Code.[21] The FAQ also noted that under section 1304(b)(4)(D) of the Affordable Care Act and § 155.710(d), when a small employer participating in a SHOP ceases to be a small employer solely by reason of an increase in the number of its employees, it will continue to be treated as a small employer for purposes of SHOP participation for as long as it continues to purchase coverage through the SHOP, and the issuer should treat such an employer as a small employer for purposes of risk adjustment. We note that nothing in this proposal supersedes or conflicts with the option under section 1312(f)(2)(B)(i) of the Affordable Care Act, which would allow large employers to participate in a SHOP, at the option of a State.

In the FAQ, HHS also clarified that for the risk corridors program, the issuer should use the employee counting method used to determine group size under State law (see § 153.510(f)). However, under section 1304(b)(4)(D) of the Affordable Care Act and § 155.710(d), when a small employer participating in a SHOP ceases to be a small employer solely by reason of an increase in the number of its employees, it will continue to be treated as a small employer for purposes of SHOP participation for as long as it continues to purchase coverage through the SHOP, and the issuer should treat such an employer as a small employer for purposes of risk corridors.

We seek comment on this proposal.

3. Provisions and Parameters for the Permanent Risk Adjustment Program

In subparts D and G of 45 CFR part 153, we established standards for the administration of the risk adjustment program. The risk adjustment program is a program created by section 1343 of the Affordable Care Act that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. In accordance with § 153.310(a), a State that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf.

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[18] OMB Report to the Congress on the Joint Committee Reductions for Fiscal Year 2017 (Feb. 9, 2016). Available at: *https://www.whitehouse.gov/sites/default/files/omb/assets/legislative_reports/sequestration/jc_sequestration_report_2017_house.pdf.*

[19] 45 CFR 155.20 defines a large employer, in connection with a group health plan with respect to a calendar year and a plan year, as an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a large employer is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year. A State may elect to define large employer by substituting "101 employees" for "51 employees." The number of employees must be determined using the method set forth in section 4980H(c)(2) of the Code.

[20] FAQs #15450 and #15449, published on April 12, 2016 available at: *https://www.regtap.info/faq_viewu.php?id=15450* and *https://www.regtap.info/faq_viewu.php?id=15449.*

[21] See 79 FR 8544.

On March 31, 2016, HHS convened a public conference to discuss potential updates to the HHS risk adjustment methodology for the 2018 benefit year and beyond. Prior to the conference, we also issued a White Paper that was available for public comment.[22] The conference and White Paper focused on what we have learned from the 2014 benefit year of the risk adjustment program, and specific areas of potential refinements to the methodology, including prescription drug modeling, addressing partial year enrollment, future recalibrations using risk adjustment data, and a discussion of the risk adjustment transfer formula. We received numerous thoughtful and substantive comments to the White Paper and at the conference, which directly informed the policy proposals in this Payment Notice.

a. Risk Adjustment Applied to Plans in the Individual and Small Group Markets (§ 153.20)

Section 1312(c) of the Affordable Care Act directs issuers to use a single risk pool for a market—the individual or small group market—when developing rates and premiums. Section 1312(c)(3) of the Affordable Care Act gives States the option to merge the individual and small group market into a single risk pool. To align risk pools for the risk adjustment program and rate development, we stated in the 2014 Payment Notice that we would merge markets when operating risk adjustment on behalf of a State if the State elects to do the same for single risk pool purposes.[23] When the individual and small group markets are merged, we stated that the State average premium would be the average premium of all applicable individual and small group market plans in the applicable risk pool, and calculations under the transfer equation would occur across all plans in the applicable risk pool in the individual and small group markets.

Under the section 1312(c)(3) definition of a merged market and its implementing regulations at §§ 156.80 and 147.104, issuers in a merged individual and small group market must offer the same plans at the same rates to all applicants in the merged market, must offer coverage on a calendar year basis, and may not make quarterly rate adjustments to rates for small group market plans. Some States with markets that are not merged under the Federal merged market provisions require issuers to use a combined individual and small group experience to establish a market-adjusted index rate, but separate the markets for applying plan adjustment factors and for other purposes. This allows small group issuers to make quarterly rate changes that would not otherwise be allowable under the definition at section 1312(c)(3).

Because States that use a combined individual and small group experience to establish a market-adjusted index rate operate in large part as a merged market for purposes of rate setting, we believe they should be risk adjusted as merged markets if the State so elects. Risk adjustment directly impacts rate setting, and as such, should reflect the markets in which States allow issuers to set premiums. Beginning for 2017 benefit year risk adjustment, when HHS will operate risk adjustment on behalf of all States, we propose to expand our interpretation of merged market for purposes of HHS risk adjustment as described in the 2014 Payment Notice to include States that meet the definition of merged market at section 1312(c)(3), as well as States that use a combined individual and small group experience to establish a market-adjusted index rate. HHS will communicate with States that use a combined individual and small group experience to establish a market-adjusted index rate to determine whether they elect to be treated as a merged market for purposes of HHS risk adjustment. We seek comment on this proposal.

b. Overview of the HHS Risk Adjustment Model (§ 153.320)

The HHS risk adjustment model predicts plan liability for an average enrollee based on that person's age, sex, and diagnoses (risk factors), producing a risk score. The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for cost differences in each of these age groups. In each of the adult and child models, the relative costs assigned to an individual's age, sex, and diagnoses are added together to produce a risk score. Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of its diagnoses. If applicable, the risk score for adults, children, or infants is multiplied by a cost-sharing reductions adjustment.

The enrollment-weighted average risk score of all enrollees in a particular risk adjustment covered plan, also referred to as the plan liability risk score, within a geographic rating area is one of the inputs into the risk adjustment payment transfer formula, which determines the payment or charge that an issuer will receive or be required to pay for that plan. Thus, the HHS risk adjustment model predicts average group costs to account for risk across plans, which accords with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

c. Proposed Updates to the Risk Adjustment Model (§ 153.320)

For the 2018 benefit year risk adjustment model, HHS will continue to incorporate the methodological improvements finalized in the 2017 Payment Notice, such as incorporating preventive services in our simulation of plan liability and using more granular trend rates that better reflect the growth in specialty drug expenditures and drugs generally as compared to medical and surgical expenditures. Consistent with our discussion in the White Paper, we are proposing a number of updates to the risk adjustment model, including: (1) Adjustment factors for partial year enrollment; (2) prescription drug utilization factors; and (3) modifying transfers to account for high-cost enrollees. We also propose to recalibrate our risk adjustment models using the most recent available data following the publication of the final Payment Notice for the applicable benefit year, and seek comments on other considerations to improve the model's risk prediction in future rulemaking.

i. Partial Year Enrollment

After the 2014 benefit year of risk adjustment, we received feedback indicating that some issuers experienced higher than expected claims costs for partial year enrollees. We sought comment in the 2017 Payment Notice on how the risk adjustment methodology could be adjusted to more directly reflect the experience of partial year enrollees, and we received comments generally supporting an adjustment addressing partial year enrollees in the risk adjustment model. We also received feedback to the White Paper that some believe the methodology does not fully capture the risk associated with enrollees with chronic conditions who may not have accumulated diagnoses in their partial year of enrollment.

In general, we believe that individual and small group health plans are risk adjusted accurately under the HHS risk adjustment methodology. In light of our experience with the 2014 benefit year, we have observed that risk adjustment may not fully account for when a plan's enrollees differ substantially from the market average with respect to characteristics that are not adjusted for in the risk adjustment model. For example, if a plan has an enrollee population with enrollment duration that differs from the market average, and the risk associated with the enrollment duration is not fully captured through other aspects of the methodology, then for that plan, partial year enrollment may not be fully accounted for in the HHS risk adjustment methodology. As we noted in the White Paper, if the risk adjustment methodology does not fully capture risk for partial year enrollment, and if the plan had lower than average enrollment duration, the plan's risk score might be lower than it might have been otherwise.[24]

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[22] March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting: Discussion Paper (Mar. 24, 2016). Available at *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.*

[23] See 78 FR at 15419.

As we discussed in the White Paper, we reviewed the predicted expenditures, actual expenditures, and predictive ratios (that is, the ratios of predicted to actual weighted mean plan liability expenditures) by enrollment duration groups (for each: 1 Month, 2 months, and so on up to 12 months) annualized for 2014 MarketScan® adults in our risk adjustment concurrent modeling sample. We found that actuarial risk for all adult enrollees with short enrollment periods tends to be slightly under predicted, and for adult enrollees with full enrollment periods (12 months) tends to be over predicted in our methodology. One potential explanation for these results is that because risk adjustment is calculated on a per member per month basis, the model predicts costs for chronic conditions, which are often spread more evenly over time, better than costs for sudden acute events, which are often concentrated in a small number of months, when the enrollment is only for part of the year.

We discussed various approaches to address this issue in the White Paper, including the use of additional factors and the use of wholly separate models that account for duration of enrollment and metal level.

There was a broadly held preference among commenters to the White Paper for adding enrollment duration (for each: 1 Month, 2 months, and so on up to 11 months[25]) binary indicator variables as additional risk factors, as opposed to separate models based on enrollment duration. After reviewing this feedback, we announced on June 8, 2016, that we intended to propose that, beginning for the 2017 benefit year, the risk adjustment model include adjustment factors for partial year enrollees in risk adjustment covered plans.[26]

Based on analysis we performed on the MarketScan® data, the use of additional risk factors by number of enrollment months that decrease monotonically as the number of months of enrollment increases (with 12 months being the reference group) appears to best address partial year enrollment in the risk adjustment model in the short term, starting in 2017. We also believe that our proposal to add prescription drug utilization in the risk adjustment model will capture additional costs for partial year enrollees beginning in the 2018 benefit year (see discussion below).

We are proposing to recalibrate the 2017 risk adjustment adult model to reflect the incorporation of partial year enrollment duration (ED) factors. Those factors are labeled "ED_01 . . . ED_11" in the list of factors for the 2017 risk adjustment adult model at the bottom of Table 3 below.[27] We are proposing to incorporate partial year ED factors in the risk adjustment model methodology for the reasons discussed above, starting with the 2017 benefit year. We are proposing to amend our regulations at § 153.320(a)(1) to allow for HHS to make this update for the 2017 benefit year. Currently, this provision states that a risk adjustment methodology must be Federally certified, and one way a risk adjustment methodology may become Federally certified is to be developed by HHS and published in the annual HHS notice of benefit and payment parameters for the applicable benefit year. We propose to change this provision to state that the methodology may be developed by HHS and published in rulemaking in advance of the benefit year. While HHS would generally make changes to the risk adjustment methodology in the annual HHS notice of benefit and payment parameters for the applicable benefit year, under this rule, in cases where we have identified a change that we can implement prior to the benefit year, and where we can provide issuers with sufficient notice and detail on the proposed change so that issuers may reasonably account for the change, HHS would have the authority to implement the change prior to the beginning of the applicable benefit year in other rulemaking. For our proposed change to address partial year enrollment, we notified issuers of our intent to propose this change in prior guidance, and provided significant detail on the policy.[28] We seek comment on this approach.

We are also proposing to incorporate partial year enrollment duration factors in the 2018 risk adjustment adult model. Those factors are labeled "ED_01, . . . ED_11" in the list of factors for the 2018 risk adjustment adult model near the bottom of Table 4. We seek comment on recalibrating the adult models for the 2017 and 2018 benefit years to address partial year enrollment.

We are not making this change in the child and infant models as those models are based on a smaller dataset that does not provide adequate representation of partial year enrollment in these populations. We will reassess both the proposed partial year enrollment adjustment methodology, and whether we can make this adjustment in the child and infant models in the future. We also intend to continue to explore approaches under which we would use separate models for enrollees with different enrollment durations, rather than including partial year enrollment factors in the risk adjustment model, and may implement such an approach in future years. While we do not believe, based on the current data available and the analyses we have been able to perform, that using separate models for each enrollment duration is currently feasible, we believe that using separate models may better capture how the pattern of costs associated with particular diagnoses varies across enrollees with different enrollment durations, particularly for sudden acute events.

ii. Prescription Drug Hybrid Model

As discussed in the White Paper, HHS has been considering whether to propose the incorporation of prescription drug utilization indicators into the HHS risk adjustment model, beginning for the 2018 benefit year, to create a "hybrid" drug-diagnosis risk adjustment model. We are aware that there are advantages and disadvantages to including prescription drug utilization indicators in the HHS risk adjustment model and we seek comment on our proposal.

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[24] White Paper at p. 36. Available at: *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.*

[25] Twelve months is the reference group and therefore is not included.

[26] Available at: *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/RA-OnsiteQA-060816.pdf.*

[27] This table replaces Table 1 published at 81 FR 12220–12223 as the final adult model for the 2017 benefit year.

[28] See *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/RA-OnsiteQA-060816.pdf.*

Many commenters to the White Paper stated that drug information can effectively indicate health risk in cases where diagnoses may be missing. For example, diagnoses may be missing if clinicians fail to enter the condition on a patient's chart, or if there is stigma associated with certain health conditions that leads providers not to record these diagnoses on claims, or if the enrollee simply does not visit a physician during the term of his or her enrollment. However, even in these cases, prescriptions may be filled, providing information on health status.

Drug utilization patterns can also provide information on the severity of the illness. The hierarchical condition categories (HCCs) already capture information about illness severity from diagnoses, but drugs can potentially measure the severity of illness within a given HCC. A patient may receive first, second, or third lines of treatment involving different medications that indicate increasing levels of severity.

Additionally, commenters have noted that drug data can be available sooner and more easily than diagnoses from medical claims. In addition, commenters have noted that because prescription drug data is standardized, it is particularly useful for calibrating and measuring health risk because the prescription drug data will have less variability in coding.

Incorporating prescription drug utilization into the risk adjustment model will help reflect costs incurred by plans for medications for their enrollees in plans' risk scores.

Adding drug data to a diagnosis-based model also introduces operational complexities. Clinical indications for drugs can change quickly, which requires frequent updates to the model calibration and possibly to the therapeutic classification groupings as well. Because the model is calibrated before the start of the benefit year, it may be difficult to assess all updates or upcoming utilization pattern changes. Additional data requirements increase the administrative burden associated with calibrating and applying the model. Issuers of risk adjustment covered plans would be required to report prescription drug utilization as well as diagnoses, and audit and verification of the reported data would be necessary.

We have also indicated our concern that incorporating prescription drug utilization in the model may provide an incentive to overprescribe medications. Drug models may be particularly susceptible to this sort of behavior when there are inexpensive drugs included in therapeutic classes that are statistically linked to high total medical expenditures; in these situations, a small cost to the insurance plan (reimbursement for the drug) can bring a relatively large increase in revenue through the risk adjustment program.

In analyzing if and how to propose to use drug data in the risk adjustment model, we sought to strike a reasonable balance between increasing predictive accuracy and reducing incentives for overprescription. One way we sought to do so was by focusing on drugs for which guidelines on when they should be prescribed are clear. However, substantial uncertainty or disagreement across providers exists over the circumstances in which drugs should be prescribed.

In addition, incorporating drug utilization makes risk adjustment sensitive to variations in drug utilization patterns that exist for reasons other than enrollee health status. Health plans with lower prescribing rates, for example health plans primarily covering individuals in rural areas with low access to pharmacies, would incorrectly appear to have healthier populations, and would pay higher risk charges or receive lower risk payments. Other things being equal, drug utilization is expected to be lower in plans with higher cost sharing (such as bronze or silver plans) and with aggressive drug utilization management, such as prior authorization, step therapy, quantity limits, restrictive formularies, and more stringent requirements to qualify for coverage of expensive drugs.

Furthermore, the lack of clear, one-to-one associations between most drug classes and diagnoses makes development of a "hybrid" drug-diagnosis risk adjustment model that incorporates and integrates drug and diagnosis risk markers challenging.

Few drug classes are indicated for only one medical condition. Many drug classes are widely prescribed "off label" for indications that are not U.S. Food and Drug Administration (FDA)-approved. Utilization of such drug classes can have very different implications for health care expenditures depending on the reasons for which they are prescribed. Presence of a drug class may not discriminate between high and low cost individuals if it is used for both high and low cost conditions. Some drug classes may be used both for diagnoses that have been included in the HHS–HCC model, as well as for diagnoses that have been intentionally excluded, making it problematic to maintain this distinction in a hybrid drug-diagnosis risk adjustment model. Specific drugs within a drug class may have varying indications; the utilization of such drug classes may not unambiguously indicate the presence of a specific diagnosis.

Acknowledging all of the above considerations, we indicated in the June 8, 2016, guidance noted above that we intend to propose to incorporate a small number of prescription drug classes as predictors in the HHS risk adjustment methodology for the 2018 benefit year to impute missing diagnoses and to indicate severity of illness.[29] We propose to incorporate a small number of prescription drugs in the risk adjustment model for the 2018 benefit year. We are proposing this change to the model with substantial attention to the concerns presented above in determining which drug groups to include and exclude, and the proposed model type used for each drug-diagnosis pair. To ensure this change to the model does not inadvertently increase the perverse incentives described above, we will monitor and evaluate the impact of incorporating prescription drugs in the model on utilization patterns. Using the enrollee-level data that we are proposing to collect in § 153.610, in addition to other relevant data sources, we would seek to evaluate whether incorporation of drugs in the model affects the utilization of drugs included in the model. Based on our evaluation, we would add or remove drug diagnosis pairs to or from the model for future benefit years through notice and comment rulemaking. We seek comment on this proposal.

To develop hybrid drug-diagnosis risk adjustment models, we need a manageable number of clinically and empirically cohesive drug classes. We created several Prescription Drug Categories (RXCs) to select and group the drugs to be included in a hybrid diagnoses-and-drugs risk adjustment model.

Each prescription drug is assigned a National Drug Code (NDC) maintained by the FDA. There are over 190,000 NDCs, which include prescription drugs as well as over-the-counter medications. NDC codes are reported in prescription drug claims data. Due to the large number of individual NDCs, it is necessary to use a therapeutic classification system that classifies individual NDCs into aggregated categories of related drugs used for similar therapeutic purposes, or having similar pharmacological properties.

In the White Paper, we had initially based the RXCs on the American Hospital Formulary Service

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[29] Available at: *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/RA-OnsiteQA-060816.pdf.*

Pharmacologic-Therapeutic Classification©, which is published by the Board of the American Society of Health-System Pharmacists®. We chose at that point to use the American Hospital Formulary Service classification because it is widely used, widely available, comprehensive, and regularly updated. Because the American Hospital Formulary Service classification and mappings from NDCs are proprietary, however, we determined that using the United States Pharmacopeia (USP) classification would be better suited for use with HHS risk adjustment to maintain consistency with the essential health benefits requirements and for public access and transparency. The USP classification also provides chemical ingredient level identifications for drug classifications; that is, unlike American Hospital Formulary Service, USP includes comparable levels of detail to identify and group drugs used for only one diagnosis with other drugs used for multiple diagnosis codes. NDC codes are classified into 153 USP therapeutic classes. Drawing on the principles and criteria described below, we selected appropriate USP therapeutic classes and combined and edited those classes in order to create "payment" RXCs, each of which is closely associated with a specific HCC or group of HCCs that are potentially suitable for inclusion in a payment risk adjustment model. Most USP classes are somewhat heterogeneous. To designate a class of drugs to serve as an indicator that a medical diagnosis is present, we needed to comprehensively review the drugs in each USP class to select only those that are closely associated with the diagnosis.

The development of a hybrid HHS–HCC risk adjustment model requires selecting drug-diagnosis pairs (RXC–HCC pairs) to include in the model. Similar to our approach in the 2014 Payment Notice when initially determining the HCCs to be included in the HHS risk adjustment models, we used a set of principles to guide our decision making. Development of the RXC–HCC pairs was an iterative process that required recurring consultations with a panel of clinician consultants.

Principle 1—RXC categories should be clinically meaningful. Each RXC is composed of a set of NDCs. These codes should all relate to a reasonably well-specified pharmacologic, therapeutic or chemical characteristic that defines the category. RXCs must be sufficiently clinically specific to minimize opportunities for discretionary coding. Clinical meaningfulness improves the face validity of the classification system to clinicians and the model's interpretability.

Principle 2—RXCs should predict total medical and drug expenditures. NDCs in the same RXC should be reasonably homogeneous with respect to their effect on current year costs.

Principle 3—RXCs that will affect payments should have adequate sample sizes to permit accurate and stable estimates of expenditures. RXCs used in establishing payments should have adequate sample sizes in available datasets. For example, it is difficult to reliably determine the expected cost of extremely rare categories.

Principle 4—In creating an individual's clinical profile, hierarchies should be used to characterize the person's illness level within each RXC where appropriate, while the effects of unrelated prescriptions accumulate. Because each new medical event adds to an individual's total disease burden, unrelated prescriptions in different RXCs should increase predicted costs of care. However, the most severe manifestation of a given disease process principally defines its impact on costs. Therefore, related RXCs should be treated hierarchically, with those associated with more severe manifestations of a condition dominating (and eliminating the effect of) less serious ones.

Principle 5—Providers should not be penalized for prescribing additional NDCs (monotonicity). This principle has two consequences for modeling: (1) No RXC should carry a negative payment weight; and (2) an RXC that is higher-ranked in a drug hierarchy (causing lower-rank drugs in the same hierarchy to be excluded) should have at least as large a payment weight as lower-ranked RXCs in the same hierarchy.

Principle 6—The classification should assign NDCs to only one RXC (mutually exclusive classification). Because each NDC can map to more than one RXC, the classification should map NDCs to the primary RXC based on considerations such as route of administration, intended application of the product, ingredient list identifier, label, dosage form, and strength of the drug.

Principle 7—Discretionary and non-credible drug categories should be excluded from payment models. RXCs that are particularly subject to intentional or unintentional discretionary prescribing variation or inappropriate prescribing by health plans or providers, or that are not clinically or empirically credible as cost predictors, should not be included. Excluding these RXCs reduces the sensitivity of the model to prescribing variation, prescribing proliferation, and gaming.

We used clinical and statistical assessments to appropriately balance all seven principles. In designing the RXCs, principles 5 (monotonicity) and 6 (mutually exclusive classification), were generally followed. Clinical meaningfulness (principle 1) is often best served by creating a very large number of detailed clinical groupings. However, a large number of groupings conflicts with adequate sample sizes for each category (principle 3). We approached the balancing of our principles by designing a drug classification system using empirical evidence on frequencies and predictive power; clinical judgment on relatedness, specificity, and severity of RXCs; and professional judgment on incentives and likely provider responses to the classification system. The RXC risk adjustment model balances these competing goals to achieve prescription drug-based classes for use in risk adjustment.

In addition to following the set of principles described above, we carefully considered selection of high-cost drugs, to avoid overly reducing the incentives for issuers to strive for efficiency in prescription drug utilization. We also carefully considered selection of drugs in areas exhibiting a rapid rate of technological change, as a drug class that is associated with a specific, costly diagnosis in one year may no longer be commonly used for that condition the next, in which case the cost predictions based on previous years of data would be inaccurate.

Based on these considerations, we propose a small number of drug-diagnosis pairs for the proposed hybrid model. We selected RXCs to impute diagnoses and to indicate the severity of diagnoses otherwise indicated through medical coding. We worked with clinician consultants to tailor the RXCs used for imputation based on their expertise in treatment patterns as well as statistical indicators such as positive predictive value. Clinicians also informed our determination of RXCs for use as severity-only indicators in the model. For the severity-only RXCs, the presence of a prescription in the drug class signals a more severe case of the related diagnosis, which is likely to incur greater medical expenditures relative to someone with the same diagnosis, but not the drug. Severity-only RXCs are not specified in the model to impute the associated diagnosis when an HCC is not present. We are proposing limiting the number of prescription drug classes included as predictors to only those drug classes where the risk of unintended effects on provider prescribing behavior is low; as described above, we intend to monitor prescription drug utilization for unintended effects and may remove drug classes based on such evidence in future rulemaking.

Table 2 shows the list of RXC–HCC pairs that we propose to include in the initial hybrid model. Each pair is designated as either an imputation/severity or a severity-only relationship. For each pair, Table 2 shows the coefficient for the diagnosis (HCC), the drug utilization (RXC), and both.

The drug-diagnosis pairs can include more than one HCC. For example, the list includes a diabetes drug-diagnosis relationship that includes three HCCs (diabetes with acute complication, diabetes with chronic complication, and diabetes without complication) which are grouped together in the model estimation. This RXC can be interpreted as an indication that the individual should have a diagnosis of one of these three diabetes HCCs. In addition, an RXC can be linked in the model to more than one HCC, and vice-versa. For example, RXC 8 (Immune suppressants and immunomodulators) has an imputation/severity relationship with HCC 056 (Rheumatoid arthritis and specified autoimmune disorders), and also has a severity-only relationship with HCC 048 (Inflammatory bowel disease).

While ten of the RXC–HCC pairs have three levels of incremental predicted costs (diagnosis only, prescription drug only, both diagnosis and prescription drug), indicating that they can be used to impute a particular condition, the model also includes two RXC–HCC pairs that will be used for severity only—that is, they will predict incremental costs for enrollees with the diagnosis only, and with both the diagnosis and the prescription drug. There are no additional costs predicted for an enrollee taking the drug who lacks the associated diagnosis. Table 2 lists the RXC–HCC pairs we are proposing to incorporate in the adult models for the 2018 benefit year. Table 4 incorporates the full set of HCCs and RXC–HCCs and their associated coefficients that we are proposing to implement in the 2018 adult models.

TABLE 2—DRUG-DIAGNOSIS (RXC–HCC) PAIRS CHOSEN FOR THE HYBRID RISK ADJUSTMENT MODELS

RXC	RXC Label	HCC	HCC Label	Proposed RXC use
1	Hepatitis C Antivirals	037C, 036, 035, 034	Chronic Hepatitis C, Cirrhosis of Liver, End-Stage Liver Disease, and Liver Transplant Status/Complications.	imputation/severity.
2	HIV/AIDS Antivirals	001	HIV/AIDS	imputation/severity.
3	Antiarrhythmics	142	Specified Heart Arrhythmias	imputation/severity.
4	End Stage Renal Disease (ESRD) Phosphate Binders.	184, 183, 187, 188	End Stage Renal Disease, Kidney Transplant Status, Chronic Kidney Disease, Stage 5, Chronic Kidney Disease, Severe (Stage 4).	imputation/severity.
5	Anti-inflammatories for inflammatory bowel disease (IBD).	048, 041	Inflammatory Bowel Disease, Intestine Transplant Status/Complications.	imputation/severity.
6a	Anti-Diabetic Agents, Except Insulin and Metformin Only.	019, 020, 021, 018	Diabetes with Acute Complications, Diabetes with Chronic Complications, Diabetes without Complication, Pancreas Transplant Status/Complications.	imputation/severity.
6b	Insulin	019, 020, 021, 018	Diabetes with Acute Complications; Diabetes with Chronic Complications; Diabetes without Complication, Pancreas Transplant Status/Complications.	imputation/severity.
7	Multiple Sclerosis Agents	118	Multiple Sclerosis	imputation/severity.
8	Immune Suppressants and Immunomodulators.	056, 057, 048, 041	Rheumatoid Arthritis and Specified Autoimmune Disorders, Systemic Lupus Erythematosus and Other Autoimmune Disorders, Inflammatory Bowel Disease, Intestine Transplant Status/Complications.	imputation/severity.
9	Cystic Fibrosis Agents	159, 158	Cystic Fibrosis, Lung Transplant Status/Complications.	imputation/severity.
10	Ammonia Detoxicants	036, 035, 034	Cirrhosis of Liver, End-Stage Liver Disease, Liver Transplant Status/Complications.	severity-only.
11	Diuretics, Loop and Select Potassium-Sparing.	130, 129, 128	Congestive Heart Failure, Heart Transplant, Heart Assistive Device/Artificial Heart.	severity-only.

We propose to incorporate the RXC–HCC pairs—some of which are used to impute a diagnosis and calibrate the severity of the condition, and others of which are used only as an indication of severity—into the adult risk adjustment model, beginning in the 2018 benefit year. We intend to evaluate the effects of this change to determine whether to continue, broaden, or reduce this set of factors in the HHS risk adjustment models. We seek comment on this approach, including comments on the list of RXC–HCC pairs.

iii. High-Cost Risk Pooling

The HHS risk adjustment model reflects the average cost for individuals with a given set of demographic characteristics and diagnoses. Our experience with the 2014 benefit year risk adjustment demonstrated the model may underpredict costs for extremely high-cost enrollees since predicted plan liabilities reflect the average costs for individuals with the set of demographic characteristics and diagnoses included in the model. As a consequence, even with risk adjustment in place, issuers may retain an incentive to engage in risk selection in order to avoid these very high-cost enrollees (called "high-cost enrollees" throughout this proposal). Recent research has shown that adjusting for high-cost enrollees in a risk adjustment model benefits the model fit and predictive ability for the remaining risk population.[30] To mitigate any residual incentive for risk selection to avoid high-cost enrollees, and to ensure that the actuarial risk of a plan with high-cost enrollees is better reflected in the risk adjustment transfers to issuers with high actuarial risk, we propose to alter the risk adjustment methodology to better account for high-cost enrollees so that transfers resulting from the risk adjustment methodology from high actuarial risk plans to low actuarial risk plans better reflect the actuarial risk of risk adjustment covered plans in a market, across all States. We also seek to offset the need for issuers to build large risk premiums into their rates to account for these cases by giving issuers greater predictability on expenditures.

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[30] Schillo, S., G. Lux, J. Wassem and F. Buchner (2016) "High Cost Pool or High Cost Groups—How to Handle Highest Cost Cases in a Risk Adjustment Mechanism?" Health Policy (120): 141–147.

To account for the incorporation of high-cost risk in the risk adjustment model, we propose to adjust the risk adjustment model for high-cost enrollees by excluding a percentage of costs above a certain threshold level in the calculation of enrollee-level plan liability risk scores so that risk adjustment factors are calculated without the high-cost risk. Secondly, to account for the issuers' actuarial risk for costs associated with the high-cost enrollees, we would apply an adjustment for each issuer of a risk adjustment covered plan to account for a percentage of all high-cost enrollees' costs above the threshold. We would set the threshold and percentage of costs at a level that would continue to incentivize issuers to control costs while improving the risk prediction of the risk adjustment model. Issuers with the high-cost enrollees would receive an adjustment to account for actuarial risk for the percentage of costs above the threshold in their respective transfers. Using claims data submitted to the EDGE server by issuers of risk adjustment covered plans, HHS will calculate the total amount of paid claims costs for high-cost enrollees above the threshold. HHS would then calculate an adjustment as a percent of the issuer's total premiums in the respective market, which would be applied to the total transfer amount in that market, maintaining the balance of payments and charges within the risk adjustment program. We are proposing a uniform percentage of premium adjustment across all States for the individual (including catastrophic and non-catastrophic plans and merged market plans) and small group markets. We believe pooling across all States for purposes of calculating this adjustment would be most effective in reducing the impact of high-cost enrollees to better reflect actuarial risk, and seek comment on this proposal. Creating a uniform pool of high-cost enrollees, by risk pool or market, could result in some States or geographic areas subsidizing issuers with high-cost enrollees in other States or geographic areas, as we discussed at the conference and commenters to the White Paper noted. We believe pooling high-cost enrollees across all States on whose behalf we are operating the risk adjustment program could prevent certain States with high-cost enrollees from bearing a disproportionate amount of unpredictable risk.

In the White Paper we discussed a threshold of $1 million and a coinsurance rate of 80 percent (where the issuer would be liable for 20 percent of costs above $1 million for an enrollee). Commenters expressed concerns about the potential for issuers to "game" this policy by shifting costs to the risk adjustment program, and not pay sufficient attention to cost containment for costs above the threshold. While we believe these inordinately high costs reflect random risk selection for certain issuers, we are sensitive to these concerns, particularly in the first year of this adjustment in the risk adjustment model. Therefore, beginning for the 2018 benefit year, we are proposing a threshold of $2 million and a coinsurance rate of 60 percent (where the issuer would be liable for 40 percent of costs above $2 million). Beginning with the 2018 benefit year recalibration, we would also incorporate these parameters in our recalibration of the model by truncating at 40 percent of costs above $2 million in our dataset used to simulate plan liability. Doing so will produce more accurate predictive coefficients that reflect the impact of the high-cost enrollee pool. To help mitigate concerns raised, while still helping protect issuers from the unpredictable risk of exceptionally high costs, we have designed this proposal based on what we discussed at the conference and comments received on the White Paper.

As discussed above, beginning for the 2018 benefit year, we propose to adjust issuers' risk adjustment transfers by a percent of premium amount that would be determined based on the aggregate costs of the high-cost risk pool above $2 million at 60 percent coinsurance in the benefit year. This adjustment to the transfer formula would be made for all issuers of risk adjustment covered plans in the individual (including catastrophic and non-catastrophic plans and merged market plans), or small group market, across all States, based on total premiums in the respective market. We would create two high-cost risk pools across all States: One for the individual market (including catastrophic, non-catastrophic, and merged market plans), and one for the small group market. To calculate the adjustments, risk adjustment covered plans would be assessed an adjustment to fund the applicable pools and we would perform additional data quality metrics to determine an issuer's eligibility for high-cost risk pool adjustments, even if the issuer failed the data quality analysis for a risk adjustment transfer and was assessed a default charge under § 153.740(b) on that basis. At the proposed threshold and coinsurance, we expect total adjustments as a result of this policy nationally to be very small as a percent of premiums (less than one tenth of one percent of total premiums for either market). We believe the inclusion of this policy, in combination with the transfers attributable to the plan liability risk scores, will allow us to better assess total actuarial risk for each risk adjustment eligible plan, and thereby to ensure that risk adjustment is appropriately compensating issuers. We seek comment on this proposal. We also seek comment on whether to cap the adjustments if they exceed a certain amount.

iv. Other Considerations

We had previously reported that based on the commercial MarketScan® data, the HHS risk adjustment models slightly underpredict risk for low-cost enrollees, and slightly overpredict risk for enrollees with high expenditures.[31] We have received feedback that HHS should adjust the risk adjustment models for the underprediction of risk for low cost enrollees, and the overprediction of risk for enrollees with high expenditures, which affects the plan liability risk scores of plans that enroll more healthy individuals or plans that enroll more individuals with the most extreme chronic health conditions. We are considering the implementation of the following policies, beginning with the 2018 benefit year, in order to improve model performance for these subpopulations, and seek comment on these approaches. We are considering use of a constrained regression approach, under which we would estimate the adult risk adjustment model using only the age-sex variables. We would then re-estimate the model using the full set of HCCs, while constraining the value of the age-sex coefficients to be same as those from the first estimation. We believe that this two-step estimation approach would result in age-sex coefficients of greater magnitude, potentially helping us predict the risk of the healthiest subpopulations more accurately. Similarly, we are considering approaches in which our first estimation of the model would include additional independent variables intended to account for potential non-linearities in risk for the highest-risk subpopulations, and then removing those additional variables in the second estimation. We are considering creating separate models for enrollees with and without HCCs to derive two separate sets of age-sex coefficients. We believe such an approach could also help improve the models' predictive ratios for the healthiest subpopulations, though this model would have a separate set of age-sex coefficients for individuals with no HCCs and the individuals with HCCs. Finally, we are evaluating an approach in which we would directly adjust plan liability risk scores outside of the model for these subpopulations. For example, we could potentially make an adjustment to the plan liability risk scores calculated through the HHS risk adjustment models that would adjust for such an underprediction or overprediction in actuarial risk by directly increasing low plan liability risk scores and directly reducing high plan liability risk scores in order to better match the relative risks of these subpopulations. We note that while we believe modifications of this type could improve the model's performance along this specific dimension, there is a risk that such modifications could unintentionally worsen model performance along other dimensions on which the model currently performs well. For this reason, we are continuing to evaluate the effect of these types of modifications on all aspects of the model's performance before choosing to implement such an approach, and would not implement these types of modifications if we determined that doing so would have material unintended consequences for the model's performance along other dimensions. We seek comment on methods discussed above as well as other methods to improve the predictive ratios of the HHS risk adjustment models.

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[31] Available at: *https://www.cms.gov/mmrr/Downloads/MMRR2014_004_03_a03.pdf.*

In addition, we have received feedback regarding our transfer methodology in community rated States. In the 2014 Payment Notice, we stated that billable members exclude children who do not count towards family rates. In the second Program Integrity Rule, we clarified the modification to the transfer formula to accommodate community rated States that utilize family tiering rating factors. In the case of family tiering States, billable members are based on the number of children that implicitly count towards the premium under a State's family rating factors. We have received feedback that there may be alternative methodologies for calculating billable member months in family tiering States, such as by adjusting for the expected actual number of members on the policy, not the number of members that implicitly count towards the premium. We seek comment on whether our methodology for calculating billable member months in family tiering States should be altered, and how.

v. Data Timing for Risk Adjustment Recalibrations

We have used the three most recent years of MarketScan® data to recalibrate the 2016 and 2017 benefit year risk adjustment models. This approach has allowed for using the blended, or averaged, coefficients from three years of separately solved models, which promotes stability for the risk adjustment coefficients year-to-year, particularly for conditions with small sample sizes. This approach in previous years has also required that we finalize coefficients based on data that does not become available until after the publication of the proposed Payment Notice. We received several comments to the 2017 Payment Notice proposed rule requesting that the Payment Notice schedule be moved up to accommodate substantive comments and to permit issuers more time between the publication of the Payment Notice and the commencement of issuers' certification activities. In order to accommodate commenters' request for an earlier Payment Notice schedule, we would not be able to incorporate an additional recent year of data. We also received many comments on how to best address the data lag for HHS risk adjustment and better reflect new treatments that may be associated with high-cost conditions. We had discussed in the White Paper the use of only 2014 MarketScan® data for the 2018 benefit year recalibration; using blended, three year data coefficients would mitigate any introductions of new costs for particular conditions by two years of older data. However, commenters to the White Paper supported continuing to use a 3-year blend for 2018 benefit year recalibration. We are proposing to continue to use the 3-year blend for 2018 benefit year recalibration.

We noted at the conference that we were considering releasing more recent, updated final coefficients closer to the respective risk adjustment benefit year using more recent data available in guidance after the risk adjustment methodology for the corresponding benefit year has been finalized in the applicable Payment Notice. Commenters supported releasing coefficients closer to the benefit year that reflect the most recent data. We are proposing to amend our regulations at § 153.320(b)(1)(i) to allow for HHS to provide draft coefficients in an annual Payment Notice, as well as the intended datasets to be used to calculate final coefficients and the date by which the final coefficients will be released in guidance. We are considering using 2015, 2016, and 2017 MarketScan® data for 2018 risk adjustment, publishing the final, blended coefficients in the early spring of 2019, prior to final 2018 benefit year risk adjustment calculations. We have previously finalized the risk adjustment methodology, including the final coefficients prior to rate setting and benefits being provided to members. We seek comment on this proposal, specifically the timing of the release of final coefficients and whether such a practice would affect issuer expectations with respect to the methodology to be applied.

We also seek comment on the timing of the publication of the final coefficients, providing a few options to reduce the data lag as much as possible. As the first option, we could release final coefficients for the 2018 benefit year risk adjustment model in the spring of 2017 that would reflect the incorporation of 2015 MarketScan® data, after it becomes available, blended with 2013 and 2014 MarketScan®. On the other hand, we could release final coefficients for the 2018 benefit year risk adjustment model in the spring of 2019, prior to the April 30, 2019, data submission deadline for the 2018 benefit year that would reflect 2015, 2016, and 2017 blended MarketScan® data. We could also provide interim coefficients in the spring of 2018 using 2014, 2015 and 2016 blended MarketScan® data, in addition to the interim coefficients that would be published in the 2018 Payment Notice final rule using 2013 and 2014 data. As noted above, we would continue to finalize the risk adjustment methodology for the corresponding year through notice and comment in the applicable annual Payment Notice.

We seek comment on this proposal.

d. List of Factors To Be Employed in the Model (§ 153.320)

For the 2018 benefit year, in addition to the RXCs we are proposing to include in the adult risk adjustment model, we are also proposing to separate the

Chronic Hepatitis HCC into two new HCCs for Hepatitis C and Hepatitis A and B, in the adult, child, and infant models. This would increase the total HCCs in the HHS risk adjustment methodology from 127 to 128. The proposed factors resulting from the blended factors from the 2013 and 2014 separately solved models (with the incorporation of partial year enrollment and prescription drugs reflected in the adult models only) are shown in the Tables 4 through 9. The adult, child, and infant models have been truncated to account for the high-cost enrollee pool payment parameters ($2 million threshold, 60 percent coinsurance). Table 4 contains factors for each adult model, including the interactions.[32]

Table 5 contains the HHS HCCs in the severity illness indicator variable. Table 6 contains the factors for each child model. Table 6 contains the factors for each infant model.

TABLE 3—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2017 BENEFIT YEAR

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 21–24, Male	0.199	0.148	0.092	0.056	0.055
Age 25–29, Male	0.189	0.137	0.080	0.043	0.043
Age 30–34, Male	0.245	0.180	0.107	0.059	0.059
Age 35–39, Male	0.312	0.234	0.147	0.089	0.088
Age 40–44, Male	0.391	0.301	0.199	0.130	0.129
Age 45–49, Male	0.471	0.369	0.253	0.174	0.173
Age 50–54, Male	0.611	0.492	0.355	0.260	0.258
Age 55–59, Male	0.701	0.567	0.414	0.306	0.304
Age 60–64, Male	0.810	0.654	0.478	0.349	0.347
Age 21–24, Female	0.339	0.262	0.171	0.111	0.110
Age 25–29, Female	0.399	0.308	0.203	0.132	0.130
Age 30–34, Female	0.539	0.428	0.305	0.224	0.222
Age 35–39, Female	0.633	0.513	0.380	0.294	0.292
Age 40–44, Female	0.713	0.579	0.433	0.336	0.335
Age 45–49, Female	0.724	0.585	0.432	0.327	0.325
Age 50–54, Female	0.821	0.671	0.501	0.382	0.379
Age 55–59, Female	0.829	0.672	0.495	0.367	0.364
Age 60–64, Female	0.876	0.706	0.513	0.372	0.370
Diagnosis Factors					
HIV/AIDS	8.943	8.450	8.099	8.142	8.143
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	10.685	10.510	10.404	10.460	10.461
Central Nervous System Infections, Except Viral Meningitis	6.636	6.535	6.470	6.491	6.492
Viral or Unspecified Meningitis	4.664	4.428	4.269	4.227	4.227
Opportunistic Infections	8.507	8.406	8.340	8.322	8.321
Metastatic Cancer	24.307	23.874	23.573	23.632	23.633
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	12.629	12.295	12.061	12.065	12.066
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	5.852	5.617	5.440	5.393	5.392
Colorectal, Breast (Age < 50), Kidney, and Other Cancers	5.159	4.924	4.743	4.695	4.694
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	2.965	2.792	2.655	2.602	2.601
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.459	1.304	1.167	1.076	1.074
Pancreas Transplant Status/Complications	5.458	5.236	5.093	5.115	5.115
Diabetes with Acute Complications	1.192	1.053	0.929	0.825	0.824
Diabetes with Chronic Complications	1.192	1.053	0.929	0.825	0.824
Diabetes without Complication	1.192	1.053	0.929	0.825	0.824
Protein-Calorie Malnutrition	13.677	13.685	13.695	13.756	13.757
Mucopolysaccharidosis	2.285	2.165	2.066	2.013	2.013
Lipidoses and Glycogenosis	2.285	2.165	2.066	2.013	2.013
Amyloidosis, Porphyria, and Other Metabolic Disorders	2.285	2.165	2.066	2.013	2.013
Adrenal, Pituitary, and Other Significant Endocrine Disorders	2.285	2.165	2.066	2.013	2.013
Liver Transplant Status/Complications	16.044	15.870	15.760	15.773	15.773
End-Stage Liver Disease	7.110	6.870	6.712	6.730	6.731
Cirrhosis of Liver	3.856	3.694	3.572	3.538	3.537
Chronic Hepatitis	3.856	3.694	3.572	3.538	3.537
Acute Liver Failure/Disease, Including Neonatal Hepatitis	4.429	4.268	4.158	4.147	4.147
Intestine Transplant Status/Complications	32.610	32.560	32.521	32.564	32.563
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	11.825	11.566	11.387	11.416	11.417
Intestinal Obstruction	6.542	6.277	6.105	6.124	6.124

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[32] We note that the interaction factors are additive, and not hierarchical in nature—that is, an enrollee could have several, additive interactions.

TABLE 3—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2017 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Chronic Pancreatitis	5.458	5.236	5.093	5.115	5.115
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	2.710	2.522	2.385	2.337	2.336
Inflammatory Bowel Disease	3.667	3.401	3.197	3.105	3.103
Necrotizing Fasciitis	6.581	6.382	6.243	6.258	6.258
Bone/Joint/Muscle Infections/Necrosis	6.581	6.382	6.243	6.258	6.258
Rheumatoid Arthritis and Specified Autoimmune Disorders	4.854	4.592	4.399	4.389	4.389
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.212	1.077	0.957	0.872	0.871
Osteogenesis Imperfecta and Other Osteodystrophies	3.126	2.927	2.766	2.706	2.705
Congenital/Developmental Skeletal and Connective Tissue Disorders	3.126	2.927	2.766	2.706	2.705
Cleft Lip/Cleft Palate	1.310	1.149	1.020	0.952	0.951
Hemophilia	46.447	46.159	45.940	45.946	45.947
Myelodysplastic Syndromes and Myelofibrosis	12.671	12.534	12.439	12.449	12.449
Aplastic Anemia	12.671	12.534	12.439	12.449	12.449
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	9.742	9.580	9.457	9.448	9.448
Sickle Cell Anemia (Hb-SS)	9.742	9.580	9.457	9.448	9.448
Thalassemia Major	9.742	9.580	9.457	9.448	9.448
Combined and Other Severe Immunodeficiencies	5.438	5.290	5.186	5.188	5.188
Disorders of the Immune Mechanism	5.438	5.290	5.186	5.188	5.188
Coagulation Defects and Other Specified Hematological Disorders	2.810	2.712	2.631	2.603	2.603
Drug Psychosis	3.832	3.576	3.381	3.288	3.286
Drug Dependence	3.832	3.576	3.381	3.288	3.286
Schizophrenia	3.196	2.940	2.749	2.685	2.684
Major Depressive and Bipolar Disorders	1.720	1.552	1.408	1.312	1.311
Reactive and Unspecified Psychosis, Delusional Disorders	1.720	1.552	1.408	1.312	1.311
Personality Disorders	1.190	1.054	0.920	0.823	0.822
Anorexia/Bulimia Nervosa	2.704	2.537	2.400	2.342	2.341
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	2.648	2.517	2.414	2.364	2.364
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.073	0.965	0.861	0.788	0.787
Autistic Disorder	1.190	1.054	0.920	0.823	0.822
Pervasive Developmental Disorders, Except Autistic Disorder	1.190	1.054	0.920	0.823	0.822
Traumatic Complete Lesion Cervical Spinal Cord	12.012	11.856	11.742	11.739	11.740
Quadriplegia	12.012	11.856	11.742	11.739	11.740
Traumatic Complete Lesion Dorsal Spinal Cord	9.161	9.003	8.889	8.877	8.877
Paraplegia	9.161	9.003	8.889	8.877	8.877
Spinal Cord Disorders/Injuries	5.641	5.430	5.278	5.249	5.249
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	3.027	2.790	2.623	2.583	2.583
Quadriplegic Cerebral Palsy	1.229	1.016	0.855	0.791	0.790
Cerebral Palsy, Except Quadriplegic	0.135	0.073	0.039	0.016	0.015
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	0.077	0.022	0.000	0.000	0.000
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	5.252	5.104	4.998	4.975	4.975
Muscular Dystrophy	2.150	1.984	1.862	1.787	1.786
Multiple Sclerosis	13.598	13.194	12.910	12.956	12.957
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	2.150	1.984	1.862	1.787	1.786
Seizure Disorders and Convulsions	1.503	1.344	1.213	1.143	1.142
Hydrocephalus	6.394	6.272	6.171	6.144	6.144
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	9.200	9.064	8.958	8.953	8.952
Respirator Dependence/Tracheostomy Status	34.709	34.699	34.698	34.764	34.765
Respiratory Arrest	10.541	10.391	10.296	10.360	10.361
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	10.541	10.391	10.296	10.360	10.361
Heart Assistive Device/Artificial Heart	35.115	34.870	34.711	34.771	34.772
Heart Transplant	35.115	34.870	34.711	34.771	34.772
Congestive Heart Failure	3.281	3.173	3.096	3.090	3.090
Acute Myocardial Infarction	10.133	9.797	9.582	9.693	9.695
Unstable Angina and Other Acute Ischemic Heart Disease	5.231	4.955	4.782	4.796	4.797
Heart Infection/Inflammation, Except Rheumatic	6.303	6.168	6.068	6.046	6.046
Specified Heart Arrhythmias	2.834	2.685	2.569	2.515	2.515
Intracranial Hemorrhage	9.426	9.147	8.956	8.965	8.965
Ischemic or Unspecified Stroke	3.167	2.982	2.870	2.875	2.876

TABLE 3—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2017 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Cerebral Aneurysm and Arteriovenous Malformation	3.947	3.748	3.605	3.563	3.563
Hemiplegia/Hemiparesis	5.466	5.372	5.315	5.358	5.359
Monoplegia, Other Paralytic Syndromes	3.457	3.324	3.230	3.211	3.211
Atherosclerosis of the Extremities with Ulceration or Gangrene	10.936	10.837	10.782	10.850	10.852
Vascular Disease with Complications	7.731	7.546	7.419	7.419	7.420
Pulmonary Embolism and Deep Vein Thrombosis	3.845	3.678	3.558	3.531	3.531
Lung Transplant Status/Complications	36.420	36.228	36.104	36.181	36.182
Cystic Fibrosis	18.022	17.696	17.452	17.474	17.474
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.951	0.833	0.723	0.648	0.646
Asthma	0.951	0.833	0.723	0.648	0.646
Fibrosis of Lung and Other Lung Disorders	1.894	1.774	1.685	1.644	1.643
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	7.595	7.521	7.472	7.486	7.486
Kidney Transplant Status	10.187	9.922	9.747	9.738	9.738
End Stage Renal Disease	38.453	38.219	38.071	38.191	38.193
Chronic Kidney Disease, Stage 5	2.087	1.988	1.924	1.919	1.919
Chronic Kidney Disease, Severe (Stage 4)	2.087	1.988	1.924	1.919	1.919
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.357	1.170	0.991	0.806	0.803
Miscarriage with Complications	1.357	1.170	0.991	0.806	0.803
Miscarriage with No or Minor Complications	1.357	1.170	0.991	0.806	0.803
Completed Pregnancy With Major Complications	3.651	3.168	2.877	2.726	2.727
Completed Pregnancy With Complications	3.651	3.168	2.877	2.726	2.727
Completed Pregnancy with No or Minor Complications	3.651	3.168	2.877	2.726	2.727
Chronic Ulcer of Skin, Except Pressure	2.360	2.236	2.153	2.137	2.137
Hip Fractures and Pathological Vertebral or Humerus Fractures	9.462	9.246	9.102	9.137	9.138
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	2.011	1.880	1.766	1.695	1.694
Stem Cell, Including Bone Marrow, Transplant Status/Complications	31.030	31.024	31.019	31.037	31.037
Artificial Openings for Feeding or Elimination	10.041	9.948	9.888	9.926	9.927
Amputation Status, Lower Limb/Amputation Complications	5.262	5.111	5.014	5.043	5.044
Interaction Factors					
Severe illness × Opportunistic Infections	10.392	10.618	10.787	10.882	10.884
Severe illness × Metastatic Cancer	10.392	10.618	10.787	10.882	10.884
Severe illness × Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	10.392	10.618	10.787	10.882	10.884
Severe illness × Non-Hodgkin's Lymphomas and Other Cancers and Tumors	10.392	10.618	10.787	10.882	10.884
Severe illness × Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	10.392	10.618	10.787	10.882	10.884
Severe illness × Heart Infection/Inflammation, Except Rheumatic	10.392	10.618	10.787	10.882	10.884
Severe illness × Intracranial Hemorrhage	10.392	10.618	10.787	10.882	10.884
Severe illness × HCC group G06 (G06 is HCC Group 6 which includes the following HCCs in the blood disease category: 67, 68)	10.392	10.618	10.787	10.882	10.884
Severe illness × HCC group G08 (G08 is HCC Group 8 which includes the following HCCs in the blood disease category: 73, 74)	10.392	10.618	10.787	10.882	10.884
Severe illness × End-Stage Liver Disease	1.899	2.034	2.136	2.220	2.221
Severe illness × Acute Liver Failure/Disease, Including Neonatal Hepatitis	1.899	2.034	2.136	2.220	2.221
Severe illness × Atherosclerosis of the Extremities with Ulceration or Gangrene	1.899	2.034	2.136	2.220	2.221
Severe illness × Vascular Disease with Complications	1.899	2.034	2.136	2.220	2.221
Severe illness × Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	1.899	2.034	2.136	2.220	2.221
Severe illness × Artificial Openings for Feeding or Elimination	1.899	2.034	2.136	2.220	2.221
Severe illness × HCC group G03 (G03 is HCC Group 3 which includes the following HCCs in the musculoskeletal disease category: 54, 55)	1.899	2.034	2.136	2.220	2.221

TABLE 3—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2017 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Enrollment Duration Factors					
One month of enrollment	0.515	0.441	0.396	0.386	0.386
Two months of enrollment	0.454	0.381	0.329	0.318	0.318
Three months of enrollment	0.387	0.321	0.270	0.258	0.258
Four months of enrollment	0.316	0.264	0.221	0.211	0.211
Five months of enrollment	0.273	0.228	0.188	0.176	0.176
Six months of enrollment	0.248	0.208	0.170	0.156	0.156
Seven months of enrollment	0.217	0.186	0.155	0.145	0.144
Eight months of enrollment	0.166	0.142	0.118	0.110	0.109
Nine months of enrollment	0.114	0.103	0.092	0.089	0.089
Ten months of enrollment	0.114	0.103	0.092	0.089	0.089
Eleven months of enrollment	0.100	0.092	0.084	0.082	0.082

TABLE 4—DRAFT ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
	Demographic Factors					
	Age 21–24, Male	0.176	0.140	0.095	0.052	0.049
	Age 25–29, Male	0.160	0.125	0.080	0.036	0.033
	Age 30–34, Male	0.206	0.160	0.105	0.048	0.044
	Age 35–39, Male	0.270	0.215	0.148	0.079	0.074
	Age 40–44, Male	0.337	0.273	0.196	0.114	0.108
	Age 45–49, Male	0.408	0.335	0.249	0.155	0.149
	Age 50–54, Male	0.533	0.447	0.346	0.234	0.227
	Age 55–59, Male	0.608	0.510	0.397	0.272	0.264
	Age 60–64, Male	0.702	0.588	0.460	0.312	0.304
	Age 21–24, Female	0.303	0.249	0.179	0.106	0.101
	Age 25–29, Female	0.351	0.286	0.207	0.122	0.116
	Age 30–34, Female	0.485	0.405	0.312	0.214	0.209
	Age 35–39, Female	0.572	0.483	0.383	0.280	0.275
	Age 40–44, Female	0.644	0.545	0.434	0.320	0.315
	Age 45–49, Female	0.652	0.549	0.434	0.310	0.304
	Age 50–54, Female	0.738	0.627	0.501	0.361	0.353
	Age 55–59, Female	0.742	0.626	0.496	0.347	0.339
	Age 60–64, Female	0.780	0.654	0.513	0.351	0.341
	Diagnosis Factors					
HCC001	HIV/AIDS	6.183	5.760	5.473	5.469	5.539
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.	9.552	9.383	9.283	9.330	9.368
HCC003	Central Nervous System Infections, Except Viral Meningitis.	6.422	6.330	6.272	6.293	6.313
HCC004	Viral or Unspecified Meningitis	4.503	4.287	4.163	4.106	4.139
HCC006	Opportunistic Infections	7.320	7.228	7.177	7.153	7.165
HCC008	Metastatic Cancer	22.731	22.324	22.054	22.096	22.169
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	11.734	11.425	11.226	11.215	11.265
HCC010	Non-Hodgkin's Lymphomas and Other Cancers and Tumors.	5.463	5.251	5.110	5.051	5.077
HCC011	Colorectal, Breast (Age <50), Kidney, and Other Cancers.	4.767	4.556	4.412	4.350	4.375
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.	2.781	2.627	2.522	2.457	2.472
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.	1.329	1.199	1.101	0.996	1.002
HCC018	Pancreas Transplant Status/Complications.	4.775	4.576	4.459	4.475	4.514
HCC019	Diabetes with Acute Complications	0.647	0.575	0.511	0.432	0.430
HCC020	Diabetes with Chronic Complications	0.647	0.575	0.511	0.432	0.430
HCC021	Diabetes without Complication	0.647	0.575	0.511	0.432	0.430
HCC023	Protein-Calorie Malnutrition	12.908	12.906	12.897	12.961	12.969
HCC026	Mucopolysaccharidosis	2.037	1.934	1.861	1.798	1.806
HCC027	Lipidoses and Glycogenosis	2.037	1.934	1.861	1.798	1.806

TABLE 4—DRAFT ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders.	2.037	1.934	1.861	1.798	1.806
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders.	2.037	1.934	1.861	1.798	1.806
HCC034	Liver Transplant Status/Complications	11.899	11.778	11.711	11.700	11.720
HCC035	End-Stage Liver Disease	3.843	3.664	3.556	3.533	3.561
HCC036	Cirrhosis of Liver	1.336	1.218	1.144	1.089	1.101
HCC037C	Chronic Viral Hepatitis C	0.913	0.801	0.726	0.667	0.677
HCC037B	Chronic Hepatitis, Other/Unspecified	0.913	0.801	0.726	0.667	0.677
HCC038	Acute Liver Failure/Disease, Including Neonatal Hepatitis.	3.843	3.664	3.556	3.533	3.561
HCC041	Intestine Transplant Status/Complications	30.139	30.077	30.019	30.075	30.090
HCC042	Peritonitis/Gastrointestinal Perforation/ Necrotizing Enterocolitis.	10.733	10.494	10.340	10.353	10.395
HCC045	Intestinal Obstruction	6.002	5.756	5.611	5.611	5.654
HCC046	Chronic Pancreatitis	4.775	4.576	4.459	4.475	4.514
HCC047	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.	2.419	2.255	2.152	2.092	2.112
HCC048	Inflammatory Bowel Disease	2.046	1.872	1.751	1.655	1.669
HCC054	Necrotizing Fasciitis	6.007	5.828	5.710	5.716	5.748
HCC055	Bone/Joint/Muscle Infections/Necrosis	6.007	5.828	5.710	5.716	5.748
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders.	2.278	2.137	2.035	1.968	1.982
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders.	1.030	0.918	0.836	0.737	0.740
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies.	2.905	2.727	2.600	2.526	2.543
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders.	2.905	2.727	2.600	2.526	2.543
HCC063	Cleft Lip/Cleft Palate	1.143	1.002	0.908	0.827	0.839
HCC066	Hemophilia	42.231	41.976	41.792	41.785	41.825
HCC067	Myelodysplastic Syndromes and Myelofibrosis.	12.207	12.080	11.999	12.004	12.026
HCC068	Aplastic Anemia	12.207	12.080	11.999	12.004	12.026
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.	8.782	8.635	8.534	8.511	8.532
HCC070	Sickle Cell Anemia (Hb-SS)	8.782	8.635	8.534	8.511	8.532
HCC071	Thalassemia Major	8.782	8.635	8.534	8.511	8.532
HCC073	Combined and Other Severe Immunodeficiencies.	4.911	4.779	4.696	4.688	4.709
HCC074	Disorders of the Immune Mechanism	4.911	4.779	4.696	4.688	4.709
HCC075	Coagulation Defects and Other Specified Hematological Disorders.	2.568	2.480	2.417	2.380	2.388
HCC081	Drug Psychosis	3.749	3.517	3.368	3.255	3.277
HCC082	Drug Dependence	3.749	3.517	3.368	3.255	3.277
HCC087	Schizophrenia	3.103	2.871	2.722	2.639	2.668
HCC088	Major Depressive and Bipolar Disorders	1.630	1.484	1.381	1.273	1.282
HCC089	Reactive and Unspecified Psychosis, Delusional Disorders.	1.630	1.484	1.381	1.273	1.282
HCC090	Personality Disorders	1.142	1.028	0.930	0.819	0.820
HCC094	Anorexia/Bulimia Nervosa	2.692	2.539	2.431	2.367	2.382
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.	2.409	2.290	2.211	2.148	2.159
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.	0.849	0.756	0.680	0.594	0.595
HCC102	Autistic Disorder	1.142	1.028	0.930	0.819	0.820
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder.	1.142	1.028	0.930	0.819	0.820
HCC106	Traumatic Complete Lesion Cervical Spinal Cord.	11.189	11.036	10.934	10.921	10.945
HCC107	Quadriplegia	11.189	11.036	10.934	10.921	10.945
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord.	8.762	8.617	8.520	8.501	8.523
HCC109	Paraplegia	8.762	8.617	8.520	8.501	8.523
HCC110	Spinal Cord Disorders/Injuries	5.523	5.325	5.201	5.163	5.191
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.	2.567	2.353	2.220	2.162	2.191
HCC112	Quadriplegic Cerebral Palsy	1.020	0.881	0.784	0.706	0.716
HCC113	Cerebral Palsy, Except Quadriplegic	0.168	0.111	0.070	0.030	0.033
HCC114	Spina Bifida and Other Brain/Spinal/ Nervous System Congenital Anomalies.	0.046	0.000	0.000	0.000	0.000

TABLE 4—DRAFT ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	5.158	5.020	4.933	4.905	4.924
HCC117	Muscular Dystrophy	2.075	1.927	1.838	1.751	1.763
HCC118	Multiple Sclerosis	3.652	3.459	3.335	3.267	3.289
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.	2.075	1.927	1.838	1.751	1.763
HCC120	Seizure Disorders and Convulsions	1.447	1.308	1.211	1.127	1.137
HCC121	Hydrocephalus	5.884	5.771	5.685	5.652	5.667
HCC122	Non-Traumatic Coma, and Brain Compression/Anoxic Damage.	8.606	8.480	8.389	8.378	8.396
HCC125	Respirator Dependence/Tracheostomy Status.	32.063	32.042	32.021	32.093	32.106
HCC126	Respiratory Arrest	9.458	9.316	9.223	9.280	9.312
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.	9.458	9.316	9.223	9.280	9.312
HCC128	Heart Assistive Device/Artificial Heart	31.966	31.751	31.611	31.636	31.677
HCC129	Heart Transplant	31.966	31.751	31.611	31.636	31.677
HCC130	Congestive Heart Failure	2.074	1.978	1.912	1.873	1.883
HCC131	Acute Myocardial Infarction	9.396	9.079	8.878	8.975	9.044
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease.	4.759	4.510	4.368	4.366	4.412
HCC135	Heart Infection/Inflammation, Except Rheumatic.	5.703	5.585	5.507	5.477	5.492
HCC142	Specified Heart Arrhythmias	2.065	1.948	1.869	1.802	1.811
HCC145	Intracranial Hemorrhage	8.616	8.359	8.198	8.189	8.231
HCC146	Ischemic or Unspecified Stroke	2.891	2.725	2.634	2.629	2.660
HCC149	Cerebral Aneurysm and Arteriovenous Malformation.	3.677	3.501	3.391	3.335	3.357
HCC150	Hemiplegia/Hemiparesis	4.955	4.864	4.808	4.848	4.869
HCC151	Monoplegia, Other Paralytic Syndromes	3.104	2.983	2.909	2.881	2.899
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene.	9.488	9.411	9.360	9.434	9.459
HCC154	Vascular Disease with Complications	7.268	7.097	6.989	6.978	7.005
HCC156	Pulmonary Embolism and Deep Vein Thrombosis.	3.480	3.331	3.236	3.195	3.215
HCC158	Lung Transplant Status/Complications	31.358	31.201	31.097	31.176	31.215
HCC159	Cystic Fibrosis	7.004	6.736	6.550	6.529	6.569
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.	0.897	0.797	0.718	0.631	0.634
HCC161	Asthma	0.897	0.797	0.718	0.631	0.634
HCC162	Fibrosis of Lung and Other Lung Disorders.	1.730	1.624	1.557	1.508	1.518
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	6.798	6.731	6.689	6.697	6.711
HCC183	Kidney Transplant Status	7.065	6.838	6.705	6.674	6.710
HCC184	End Stage Renal Disease	23.772	23.578	23.450	23.516	23.559
HCC187	Chronic Kidney Disease, Stage 5	0.395	0.326	0.286	0.280	0.292
HCC188	Chronic Kidney Disease, Severe (Stage 4).	0.395	0.326	0.286	0.280	0.292
HCC203	Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism.	1.283	1.127	1.008	0.814	0.806
HCC204	Miscarriage with Complications	1.283	1.127	1.008	0.814	0.806
HCC205	Miscarriage with No or Minor Complications.	1.283	1.127	1.008	0.814	0.806
HCC207	Completed Pregnancy With Major Complications.	3.466	3.027	2.823	2.625	2.694
HCC208	Completed Pregnancy With Complications.	3.466	3.027	2.823	2.625	2.694
HCC209	Completed Pregnancy with No or Minor Complications.	3.466	3.027	2.823	2.625	2.694
HCC217	Chronic Ulcer of Skin, Except Pressure	2.003	1.903	1.843	1.825	1.840
HCC226	Hip Fractures and Pathological Vertebral or Humerus Fractures.	9.015	8.812	8.682	8.709	8.747
HCC227	Pathological Fractures, Except of Vertebrae, Hip, or Humerus.	2.028	1.913	1.830	1.750	1.758
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications.	28.116	28.117	28.113	28.139	28.143

TABLE 4—DRAFT ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC253	Artificial Openings for Feeding or Elimination.	9.095	9.005	8.946	8.979	8.999
HCC254	Amputation Status, Lower Limb/Amputation Complications.	4.508	4.378	4.298	4.323	4.351
Interaction Factors						
SEVERE × HCC006	Severe illness × Opportunistic Infections	9.355	9.550	9.669	9.785	9.768
SEVERE × HCC008	Severe illness × Metastatic Cancer	9.355	9.550	9.669	9.785	9.768
SEVERE × HCC009	Severe illness × Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	9.355	9.550	9.669	9.785	9.768
SEVERE × HCC010	Severe illness × Non-Hodgkin's Lymphomas and Other Cancers and Tumors.	9.355	9.550	9.669	9.785	9.768
SEVERE × HCC115	Severe illness × Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	9.355	9.550	9.669	9.785	9.768
SEVERE × HCC135	Severe illness × Heart Infection/Inflammation, Except Rheumatic.	9.355	9.550	9.669	9.785	9.768
SEVERE × HCC145	Severe illness × Intracranial Hemorrhage	9.355	9.550	9.669	9.785	9.768
SEVERE × G06	Severe illness × HCC group G06 (G06 is HCC Group 6 which includes the following HCCs in the blood disease category: 67, 68).	9.355	9.550	9.669	9.785	9.768
SEVERE × G08	Severe illness × HCC group G08 (G08 is HCC Group 8 which includes the following HCCs in the blood disease category: 73, 74).	9.355	9.550	9.669	9.785	9.768
SEVERE × HCC035	Severe illness × End-Stage Liver Disease.	1.895	2.007	2.070	2.170	2.164
SEVERE × HCC038	Severe illness × Acute Liver Failure/Disease, Including Neonatal Hepatitis.	1.895	2.007	2.070	2.170	2.164
SEVERE × HCC153	Severe illness × Atherosclerosis of the Extremities with Ulceration or Gangrene.	1.895	2.007	2.070	2.170	2.164
SEVERE × HCC154	Severe illness × Vascular Disease with Complications.	1.895	2.007	2.070	2.170	2.164
SEVERE × HCC163	Severe illness × Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	1.895	2.007	2.070	2.170	2.164
SEVERE × HCC253	Severe illness × Artificial Openings for Feeding or Elimination.	1.895	2.007	2.070	2.170	2.164
SEVERE × G03	Severe illness × HCC group G03 (G03 is HCC Group 3 which includes the following HCCs in the musculoskeletal disease category: 54, 55).	1.895	2.007	2.070	2.170	2.164
Enrollment Duration Factors						
	One month of enrollment	0.526	0.470	0.427	0.411	0.414
	Two months of enrollment	0.434	0.381	0.335	0.316	0.319
	Three months of enrollment	0.386	0.337	0.291	0.270	0.272
	Four months of enrollment	0.303	0.264	0.226	0.209	0.211
	Five months of enrollment	0.263	0.229	0.194	0.175	0.176
	Six months of enrollment	0.241	0.212	0.180	0.163	0.163
	Seven months of enrollment	0.214	0.190	0.163	0.148	0.148
	Eight months of enrollment	0.166	0.148	0.128	0.115	0.116
	Nine months of enrollment	0.111	0.100	0.089	0.085	0.085
	Ten months of enrollment	0.106	0.098	0.089	0.085	0.085
	Eleven months of enrollment	0.088	0.083	0.079	0.077	0.077
Prescription Drug Utilization Indicators						
RXC 01	Anti-Hepatitis C (HCV) Agents	23.898	23.451	23.158	23.236	23.320
RXC 02	Anti-HIV Agents	6.331	5.889	5.594	5.432	5.482
RXC 03	Antiarrhythmics	2.320	2.226	2.149	2.079	2.083
RXC 04	Phosphate Binders	13.417	13.308	13.238	13.249	13.271
RXC 05	Inflammatory Bowel Disease Agents	1.990	1.822	1.708	1.541	1.543
RXC 06b	Insulin	1.379	1.258	1.134	0.975	0.966

TABLE 4—DRAFT ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC 06a	Anti-Diabetic Agents, Except Insulin and Metformin Only.	0.575	0.502	0.428	0.326	0.319
RXC 07	Multiple Sclerosis Agents	16.971	16.286	15.836	15.832	15.945
RXC 08	Immune Suppressants and Immunomodulators.	10.134	9.586	9.234	9.242	9.339
RXC 09	Cystic Fibrosis Agents	17.443	17.133	16.931	17.071	17.144
RXC 01 × HCC37C, 036, 035, 034	Additional effect for enrollees with RXC Anti-Hepatitis C (HCV) Agents and HCC (Liver Transplant Status/Complications or End-Stage Liver Disease or Cirrhosis of Liver or Chronic Viral Hepatitis).	3.212	3.350	3.439	3.522	3.512
RXC 02 × HCC001	Additional effect for enrollees with RXC Anti-HIV Agents and HCC HIV/AIDS.	−2.238	−1.888	−1.645	−1.437	−1.465
RXC 03 × HCC142	Additional effect for enrollees with RXC Antiarrhythmics and HCC Specified Heart Arrhythmias.	−0.102	−0.076	−0.035	0.037	0.046
RXC 04 × HCC184, 183, 187, 188	Additional effect for enrollees with RXC Phosphate Binders and HCC (End Stage Renal Disease or Kidney Transplant Status or Chronic Kidney Disease, Stage 5 or Chronic Kidney Disease, Severe (Stage 4)).	7.775	7.850	7.890	7.978	7.973
RXC 05 × HCC048, 041	Additional effect for enrollees with RXC Inflammatory Bowel Disease Agents and (HCC Inflammatory Bowel Disease or Intestine Transplant Status/Complications).	−1.296	−1.208	−1.126	−1.028	−1.026
RXC 06b × HCC018, 019, 020, 021	Additional effect for enrollees with RXC Insulin and (HCC Pancreas Transplant Status/Complications or Diabetes with Acute Complications or Diabetes with Chronic Complications or Diabetes without Complication).	0.265	0.233	0.289	0.371	0.397
RXC 06a × HCC018, 019, 020, 021	Additional effect for enrollees with RXC Anti-Diabetic Agents, Except Insulin and Metformin Only and (HCC Pancreas Transplant Status/Complications or Diabetes with Acute Complications or Diabetes with Chronic Complications or Diabetes without Complication).	−0.203	−0.184	−0.141	−0.118	−0.116
RXC 07 × HCC118	Additional effect for enrollees with RXC Multiple Sclerosis Agents and HCC Multiple Sclerosis.	−1.213	−0.849	−0.619	−0.449	−0.484
RXC 08 × HCC056 or 057, and 048 or 041.	Additional effect for enrollees with RXC Immune Suppressants and Immunomodulators and (HCC Inflammatory Bowel Disease or Intestine Transplant Status/Complications) and (HCC Rheumatoid Arthritis and Specified Autoimmune Disorders or Systemic Lupus Erythematosus and Other Autoimmune Disorders).	0.022	0.024	0.038	0.012	0.009
RXC 08 × HCC056	Additional effect for enrollees with RXC Immune Suppressants and Immunomodulators and HCC Rheumatoid Arthritis and Specified Autoimmune Disorders.	−1.934	−1.747	−1.615	−1.481	−1.495
RXC 08 × HCC057	Additional effect for enrollees with RXC Immune Suppressants and Immunomodulators and HCC Systemic Lupus Erythematosus and Other Autoimmune Disorders.	−0.891	−0.759	−0.656	−0.522	−0.526
RXC 08 × HCC048, 041	Additional effect for enrollees with RXC Immune Suppressants and Immunomodulators and (HCC Inflammatory Bowel Disease or Intestine Transplant Status/Complications).	0.948	1.194	1.330	1.513	1.493

TABLE 4—Draft Adult Risk Adjustment Model Factors for 2018 Benefit Year—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC 09 × HCC159, 158	Additional effect for enrollees with RXC Cystic Fibrosis Agents and (HCC Cystic Fibrosis or Lung Transplant Status/Complications).	18.100	18.294	18.402	18.379	18.340
RXC 10 × HCC036, 035, 034	Additional effect for enrollees with RXC Ammonia Detoxicants and (HCC Liver Transplant Status/Complications or End-Stage Liver Disease or Cirrhosis of Liver).	7.113	7.080	7.054	7.145	7.164
RXC 11 × HCC130, 129, 128	Additional effect for enrollees with RXC Diuretics, Loop and Select Potassium-sparing and (HCC Heart Assistive Device/Artificial Heart or Heart Transplant or Congestive Heart Failure).	2.263	2.270	2.284	2.369	2.382

TABLE 5—HHS HCCs in the Severity Illness Indicator Variable

Description
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Peritonitis/Gastrointestinal Perforation/Necrotizing Enter colitis.
Seizure Disorders and Convulsions.
Non-Traumatic Coma, Brain Compression/Anoxic Damage.
Respirator Dependence/Tracheostomy Status.
Respiratory Arrest.
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Pulmonary Embolism and Deep Vein Thrombosis.

TABLE 6—Draft Child Risk Adjustment Model Factors for 2018 Benefit Year

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2–4, Male	0.207	0.151	0.085	0.029	0.025
Age 5–9, Male	0.142	0.102	0.053	0.011	0.008
Age 10–14, Male	0.204	0.160	0.103	0.057	0.053
Age 15–20, Male	0.271	0.220	0.158	0.102	0.098
Age 2–4, Female	0.163	0.114	0.058	0.015	0.012
Age 5–9, Female	0.116	0.081	0.039	0.008	0.006
Age 10–14, Female	0.192	0.150	0.099	0.059	0.056
Age 15–20, Female	0.309	0.250	0.177	0.109	0.104
Diagnosis Factors					
HIV/AIDS	4.686	4.277	4.006	3.895	3.948
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	15.212	15.056	14.964	14.980	15.011
Central Nervous System Infections, Except Viral Meningitis	9.957	9.790	9.682	9.681	9.708
Viral or Unspecified Meningitis	2.484	2.302	2.192	2.092	2.112
Opportunistic Infections	20.790	20.728	20.685	20.673	20.682
Metastatic Cancer	32.805	32.584	32.417	32.401	32.434
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	11.049	10.801	10.617	10.544	10.573
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	8.747	8.507	8.333	8.231	8.255
Colorectal, Breast (Age <50), Kidney, and Other Cancers	3.175	2.986	2.846	2.724	2.737
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	2.813	2.640	2.513	2.398	2.408
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.561	1.423	1.311	1.190	1.194
Pancreas Transplant Status/Complications	26.035	25.914	25.841	25.846	25.867
Diabetes with Acute Complications	2.340	2.054	1.887	1.622	1.632
Diabetes with Chronic Complications	2.340	2.054	1.887	1.622	1.632
Diabetes without Complication	2.340	2.054	1.887	1.622	1.632
Protein-Calorie Malnutrition	12.106	12.025	11.965	11.995	12.012
Mucopolysaccharidosis	8.087	7.841	7.660	7.612	7.644
Lipidoses and Glycogenosis	8.087	7.841	7.660	7.612	7.644
Congenital Metabolic Disorders, Not Elsewhere Classified	8.087	7.841	7.660	7.612	7.644

TABLE 6—DRAFT CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Amyloidosis, Porphyria, and Other Metabolic Disorders	8.087	7.841	7.660	7.612	7.644
Adrenal, Pituitary, and Other Significant Endocrine Disorders	8.087	7.841	7.660	7.612	7.644
Liver Transplant Status/Complications	26.035	25.914	25.841	25.846	25.867
End-Stage Liver Disease	11.991	11.852	11.762	11.751	11.773
Cirrhosis of Liver	9.308	9.167	9.070	9.044	9.062
Chronic Viral Hepatitis C	4.024	3.889	3.787	3.730	3.743
Chronic Hepatitis, Other/Unspecified	2.271	2.151	2.049	1.965	1.971
Acute Liver Failure/Disease, Including Neonatal Hepatitis	11.991	11.852	11.762	11.751	11.773
Intestine Transplant Status/Complications	26.035	25.914	25.841	25.846	25.867
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	13.534	13.230	13.022	13.021	13.071
Intestinal Obstruction	4.748	4.541	4.395	4.297	4.317
Chronic Pancreatitis	9.837	9.629	9.502	9.493	9.527
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	2.186	2.075	1.987	1.889	1.892
Inflammatory Bowel Disease	6.044	5.699	5.465	5.348	5.386
Necrotizing Fasciitis	3.999	3.795	3.647	3.572	3.596
Bone/Joint/Muscle Infections/Necrosis	3.999	3.795	3.647	3.572	3.596
Rheumatoid Arthritis and Specified Autoimmune Disorders	3.788	3.572	3.404	3.301	3.321
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.335	1.216	1.112	0.990	0.989
Osteogenesis Imperfecta and Other Osteodystrophies	1.489	1.379	1.285	1.201	1.206
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.489	1.379	1.285	1.201	1.206
Cleft Lip/Cleft Palate	1.502	1.322	1.192	1.064	1.075
Hemophilia	55.750	55.302	54.985	54.945	55.012
Myelodysplastic Syndromes and Myelofibrosis	15.915	15.761	15.654	15.632	15.652
Aplastic Anemia	15.915	15.761	15.654	15.632	15.652
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	7.294	7.048	6.875	6.784	6.812
Sickle Cell Anemia (Hb-SS)	7.294	7.048	6.875	6.784	6.812
Thalassemia Major	7.294	7.048	6.875	6.784	6.812
Combined and Other Severe Immunodeficiencies	6.252	6.092	5.982	5.915	5.931
Disorders of the Immune Mechanism	6.252	6.092	5.982	5.915	5.931
Coagulation Defects and Other Specified Hematological Disorders	4.546	4.429	4.333	4.257	4.264
Drug Psychosis	5.380	5.147	4.999	4.923	4.952
Drug Dependence	5.380	5.147	4.999	4.923	4.952
Schizophrenia	5.083	4.726	4.492	4.375	4.420
Major Depressive and Bipolar Disorders	1.873	1.677	1.527	1.350	1.356
Reactive and Unspecified Psychosis, Delusional Disorders	1.873	1.677	1.527	1.350	1.356
Personality Disorders	0.729	0.624	0.520	0.377	0.372
Anorexia/Bulimia Nervosa	2.892	2.708	2.576	2.504	2.524
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	3.492	3.304	3.194	3.154	3.180
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.736	1.577	1.469	1.376	1.390
Autistic Disorder	1.671	1.512	1.383	1.224	1.226
Pervasive Developmental Disorders, Except Autistic Disorder	0.835	0.726	0.612	0.447	0.437
Traumatic Complete Lesion Cervical Spinal Cord	12.558	12.507	12.489	12.562	12.579
Quadriplegia	12.558	12.507	12.489	12.562	12.579
Traumatic Complete Lesion Dorsal Spinal Cord	12.180	12.010	11.883	11.877	11.912
Paraplegia	12.180	12.010	11.883	11.877	11.912
Spinal Cord Disorders/Injuries	4.250	4.044	3.905	3.816	3.836
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	7.619	7.407	7.257	7.196	7.221
Quadriplegic Cerebral Palsy	2.991	2.764	2.631	2.634	2.675
Cerebral Palsy, Except Quadriplegic	0.778	0.617	0.514	0.422	0.436
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.275	1.146	1.054	0.976	0.986
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	8.788	8.631	8.520	8.481	8.502
Muscular Dystrophy	2.941	2.765	2.650	2.563	2.580
Multiple Sclerosis	7.769	7.471	7.263	7.206	7.246
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	2.941	2.765	2.650	2.563	2.580
Seizure Disorders and Convulsions	1.905	1.753	1.628	1.483	1.486
Hydrocephalus	4.590	4.479	4.408	4.389	4.406
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	6.647	6.522	6.434	6.385	6.397

TABLE 6—DRAFT CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Respirator Dependence/Tracheostomy Status	34.991	34.882	34.817	34.931	34.967
Respiratory Arrest	11.820	11.625	11.511	11.500	11.535
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	11.820	11.625	11.511	11.500	11.535
Heart Assistive Device/Artificial Heart	26.035	25.914	25.841	25.846	25.867
Heart Transplant	26.035	25.914	25.841	25.846	25.867
Congestive Heart Failure	6.567	6.472	6.394	6.342	6.348
Acute Myocardial Infarction	9.084	8.927	8.826	8.828	8.852
Unstable Angina and Other Acute Ischemic Heart Disease	5.051	4.971	4.917	4.926	4.938
Heart Infection/Inflammation, Except Rheumatic	14.351	14.240	14.165	14.137	14.149
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	5.764	5.584	5.432	5.305	5.313
Major Congenital Heart/Circulatory Disorders	1.573	1.475	1.361	1.239	1.235
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	1.097	1.010	0.908	0.808	0.807
Specified Heart Arrhythmias	3.684	3.526	3.401	3.320	3.333
Intracranial Hemorrhage	14.176	13.948	13.803	13.784	13.820
Ischemic or Unspecified Stroke	7.895	7.786	7.721	7.720	7.739
Cerebral Aneurysm and Arteriovenous Malformation	3.545	3.356	3.235	3.172	3.192
Hemiplegia/Hemiparesis	4.484	4.389	4.333	4.314	4.330
Monoplegia, Other Paralytic Syndromes	3.148	3.018	2.937	2.899	2.917
Atherosclerosis of the Extremities with Ulceration or Gangrene	14.633	14.377	14.225	14.131	14.168
Vascular Disease with Complications	16.113	15.969	15.873	15.876	15.899
Pulmonary Embolism and Deep Vein Thrombosis	14.661	14.521	14.435	14.448	14.475
Lung Transplant Status/Complications	26.035	25.914	25.841	25.846	25.867
Cystic Fibrosis	19.127	18.718	18.428	18.452	18.522
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.396	0.334	0.249	0.153	0.147
Asthma	0.396	0.334	0.249	0.153	0.147
Fibrosis of Lung and Other Lung Disorders	4.160	4.036	3.936	3.862	3.873
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	10.367	10.322	10.287	10.315	10.324
Kidney Transplant Status	15.081	14.777	14.581	14.566	14.616
End Stage Renal Disease	38.217	38.061	37.962	38.031	38.065
Chronic Kidney Disease, Stage 5	3.038	2.903	2.802	2.685	2.688
Chronic Kidney Disease, Severe (Stage 4)	3.038	2.903	2.802	2.685	2.688
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.033	0.878	0.754	0.549	0.541
Miscarriage with Complications	1.033	0.878	0.754	0.549	0.541
Miscarriage with No or Minor Complications	1.033	0.878	0.754	0.549	0.541
Completed Pregnancy With Major Complications	2.991	2.587	2.391	2.161	2.216
Completed Pregnancy With Complications	2.991	2.587	2.391	2.161	2.216
Completed Pregnancy with No or Minor Complications	2.991	2.587	2.391	2.161	2.216
Chronic Ulcer of Skin, Except Pressure	2.057	1.969	1.888	1.819	1.823
Hip Fractures and Pathological Vertebral or Humerus Fractures	5.729	5.486	5.302	5.192	5.214
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	1.351	1.233	1.116	0.982	0.977
Stem Cell, Including Bone Marrow, Transplant Status/Complications	26.035	25.914	25.841	25.846	25.867
Artificial Openings for Feeding or Elimination	13.409	13.305	13.251	13.357	13.391
Amputation Status, Lower Limb/Amputation Complications	7.806	7.556	7.407	7.306	7.336

TABLE 7—DRAFT INFANT RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	336.506	335.265	334.332	334.271	334.459
Extremely Immature * Severity Level 4	183.468	182.244	181.331	181.224	181.402
Extremely Immature * Severity Level 3	70.513	69.447	68.657	68.493	68.642
Extremely Immature * Severity Level 2	29.465	28.557	27.854	27.519	27.614
Extremely Immature * Severity Level 1 (Lowest)	29.465	28.557	27.854	27.519	27.614
Immature * Severity Level 5 (Highest)	178.009	176.784	175.861	175.795	175.980
Immature * Severity Level 4	80.832	79.582	78.649	78.554	78.740
Immature * Severity Level 3	45.204	44.114	43.299	43.140	43.289
Immature * Severity Level 2	29.465	28.557	27.854	27.519	27.614
Immature * Severity Level 1 (Lowest)	26.402	25.374	24.608	24.351	24.477
Premature/Multiples * Severity Level 5 (Highest)	133.590	132.392	131.511	131.378	131.555
Premature/Multiples * Severity Level 4	30.629	29.458	28.605	28.391	28.552

TABLE 7—DRAFT INFANT RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR—Continued

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Premature/Multiples * Severity Level 3	16.302	15.378	14.694	14.308	14.399
Premature/Multiples * Severity Level 2	8.445	7.691	7.131	6.599	6.637
Premature/Multiples * Severity Level 1 (Lowest)	5.825	5.277	4.774	4.196	4.187
Term * Severity Level 5 (Highest)	115.287	114.176	113.343	113.147	113.297
Term * Severity Level 4	16.144	15.252	14.603	14.155	14.235
Term * Severity Level 3	6.053	5.490	4.998	4.409	4.397
Term * Severity Level 2	3.715	3.284	2.849	2.209	2.166
Term * Severity Level 1 (Lowest)	1.570	1.351	0.965	0.436	0.387
Age 1 * Severity Level 5 (Highest)	49.286	48.692	48.242	48.122	48.198
Age 1 * Severity Level 4	8.659	8.213	7.871	7.641	7.678
Age 1 * Severity Level 3	3.182	2.901	2.635	2.374	2.380
Age 1 * Severity Level 2	1.997	1.779	1.544	1.267	1.257
Age 1 * Severity Level 1 (Lowest)	0.529	0.441	0.299	0.196	0.189
Age 0 Male	0.601	0.558	0.540	0.494	0.490
Age 1 Male	0.140	0.123	0.112	0.085	0.084

TABLE 8—HHS HCCS INCLUDED IN INFANT MODEL MATURITY CATEGORIES

Maturity category	HCC/Description
Extremely Immature	Extremely Immature Newborns, Birthweight < 500 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birthweight 500–749 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birthweight 750–999 Grams.
Immature	Premature Newborns, Including Birthweight 1000–1499 Grams.
Immature	Premature Newborns, Including Birthweight 1500–1999 Grams.
Premature/Multiples	Premature Newborns, Including Birthweight 2000–2499 Grams.
Premature/Multiples	Other Premature, Low Birthweight, Malnourished, or Multiple Birth Newborns.
Term	Term or Post-Term Singleton Newborn, Normal or High Birthweight.
Age 1	All age 1 infants.

TABLE 9—HHS HCCS INCLUDED IN INFANT MODEL SEVERITY CATEGORIES

Severity category	HCC
Severity Level 5 (Highest)	Metastatic Cancer.
Severity Level 5	Pancreas Transplant Status/Complications.
Severity Level 5	Liver Transplant Status/Complications.
Severity Level 5	End-Stage Liver Disease.
Severity Level 5	Intestine Transplant Status/Complications.
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis.
Severity Level 5	Respirator Dependence/Tracheostomy Status.
Severity Level 5	Heart Assistive Device/Artificial Heart.
Severity Level 5	Heart Transplant.
Severity Level 5	Congestive Heart Failure.
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders.
Severity Level 5	Lung Transplant Status/Complications.
Severity Level 5	Kidney Transplant Status.
Severity Level 5	End Stage Renal Disease.
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications.
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.
Severity Level 4	Mucopolysaccharidosis.
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age < 2.
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis.
Severity Level 4	Aplastic Anemia.
Severity Level 4	Combined and Other Severe Immunodeficiencies.
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord.
Severity Level 4	Quadriplegia.
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.
Severity Level 4	Quadriplegic Cerebral Palsy.
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.
Severity Level 4	Non-Traumatic Coma, Brain Compression/Anoxic Damage.
Severity Level 4	Respiratory Arrest.
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Severity Level 4	Acute Myocardial Infarction.
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic.
Severity Level 4	Major Congenital Heart/Circulatory Disorders.
Severity Level 4	Intracranial Hemorrhage.
Severity Level 4	Ischemic or Unspecified Stroke.

TABLE 9—HHS HCCS INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity category	HCC
Severity Level 4	Vascular Disease with Complications.
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis.
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.
Severity Level 4	Chronic Kidney Disease, Stage 5.
Severity Level 4	Hip Fractures and Pathological Vertebral or Humerus Fractures.
Severity Level 4	Artificial Openings for Feeding or Elimination.
Severity Level 3	HIV/AIDS.
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis.
Severity Level 3	Opportunistic Infections.
Severity Level 3	Non-Hodgkin's Lymphomas and Other Cancers and Tumors.
Severity Level 3	Colorectal, Breast (Age < 50), Kidney and Other Cancers.
Severity Level 3	Breast (Age 50+), Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.
Severity Level 3	Lipidoses and Glycogenosis.
Severity Level 3	Adrenal, Pituitary, and Other Significant Endocrine Disorders.
Severity Level 3	Acute Liver Failure/Disease, Including Neonatal Hepatitis.
Severity Level 3	Intestinal Obstruction.
Severity Level 3	Necrotizing Fasciitis.
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis.
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies.
Severity Level 3	Cleft Lip/Cleft Palate.
Severity Level 3	Hemophilia.
Severity Level 3	Disorders of the Immune Mechanism.
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders.
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord.
Severity Level 3	Paraplegia.
Severity Level 3	Spinal Cord Disorders/Injuries.
Severity Level 3	Cerebral Palsy, Except Quadriplegic.
Severity Level 3	Muscular Dystrophy.
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.
Severity Level 3	Hydrocephalus.
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease.
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders.
Severity Level 3	Specified Heart Arrhythmias.
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation.
Severity Level 3	Hemiplegia/Hemiparesis.
Severity Level 3	Cystic Fibrosis.
Severity Level 3	Fibrosis of Lung and Other Lung Disorders.
Severity Level 3	Pathological Fractures, Except of Vertebrae, Hip, or Humerus.
Severity Level 2	Viral or Unspecified Meningitis.
Severity Level 2	Thyroid, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.
Severity Level 2	Diabetes with Acute Complications.
Severity Level 2	Diabetes with Chronic Complications.
Severity Level 2	Diabetes without Complication.
Severity Level 2	Protein-Calorie Malnutrition.
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified.
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders.
Severity Level 2	Cirrhosis of Liver.
Severity Level 2	Chronic Pancreatitis.
Severity Level 2	Inflammatory Bowel Disease.
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders.
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders.
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders.
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.
Severity Level 2	Sickle Cell Anemia (Hb–SS).
Severity Level 2	Drug Psychosis.
Severity Level 2	Drug Dependence.
Severity Level 2	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.
Severity Level 2	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.
Severity Level 2	Seizure Disorders and Convulsions.
Severity Level 2	Monoplegia, Other Paralytic Syndromes.
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene.
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.
Severity Level 2	Chronic Ulcer of Skin, Except Pressure.
Severity Level 1 (Lowest)	Chronic Hepatitis.
Severity Level 1	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.
Severity Level 1	Thalassemia Major.
Severity Level 1	Autistic Disorder.

TABLE 9—HHS HCCS INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity category	HCC
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder.
Severity Level 1	Multiple Sclerosis.
Severity Level 1	Asthma.
Severity Level 1	Chronic Kidney Disease, Severe (Stage 4).
Severity Level 1	Amputation Status, Lower Limb/Amputation Complications.
Severity Level 1	No Severity HCCs.

e. Cost-Sharing Reductions (§ 153.320)

We propose to continue including an adjustment for the receipt of cost-sharing reductions in the model to account for increased plan liability due to increased utilization of health care services by enrollees receiving cost-sharing reductions. The proposed cost-sharing reductions adjustment factors for 2018 risk adjustment are unchanged from those finalized in the 2017 Payment Notice and are set forth in Table 10. These adjustments are effective for 2016, 2017, and 2018 risk adjustment, and are multiplied against the sum of the demographic, diagnosis, and interaction factors. We anticipate adjusting these factors in the annual HHS notice of benefit and payment parameters for the 2019 benefit year as additional enrollee-level data from the individual market becomes available. We seek comment on this approach.

TABLE 10—COST-SHARING REDUCTIONS ADJUSTMENT

Household income	Plan AV	Induced utilization factor
Silver Plan Variant Recipients		
100–150% of FPL	Plan Variation 94%	1.12
150–200% of FPL	Plan Variation 87%	1.12
200–250% of FPL	Plan Variation 73%	1.00
>250% of FPL	Standard Plan 70%	1.00
Zero Cost-Sharing Recipients		
<300% of FPL	Platinum (90%)	1.00
<300% of FPL	Gold (80%)	1.07
<300% of FPL	Silver (70%)	1.12
<300% of FPL	Bronze (60%)	1.15
Limited Cost-Sharing Recipients		
>300% of FPL	Platinum (90%)	1.00
>300% of FPL	Gold (80%)	1.07
>300% of FPL	Silver (70%)	1.12
>300% of FPL	Bronze (60%)	1.15

f. Model Performance Statistics (§ 153.320)

To evaluate the model's performance, we examined its R-squared and predictive ratios. The R-squared statistic, which calculates the percentage of individual variation explained by a model, measures the predictive accuracy of the model overall. The predictive ratios measure the predictive accuracy of a model for different validation groups or subpopulations. The predictive ratio for each of the HHS risk adjustment models is the ratio of the weighted mean predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The predictive ratio represents how well the model does on average at predicting plan liability for that subpopulation. A subpopulation that is predicted perfectly would have a predictive ratio of 1.0. For each of the HHS risk adjustment models, the R-squared statistic and the predictive ratio are in the range of published estimates for concurrent risk adjustment models.[33] Because we are proposing to blend the coefficients from separately solved models based on MarketScan® 2013 and 2014 data in the proposed rule, we are publishing the R-squared statistic for each model and year separately to verify their statistical validity. The R-squared statistic for each model is shown in Table 11.

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[33] Winkleman, Ross and Syed Mehmud. "A Comparative Analysis of Claims-Based Tools for Health Risk Assessment." Society of Actuaries. April 2007.

TABLE 11—R-SQUARED STATISTIC FOR HHS RISK ADJUSTMENT MODELS

Risk adjustment model	R-Squared statistic	
	2013	2014
Platinum Adult	0.4070	0.4005
Platinum Child	0.2947	0.2908
Platinum Infant	0.3354	0.3200
Gold Adult	0.4026	0.3956
Gold Child	0.2902	0.2860
Gold Infant	0.3335	0.3180
Silver Adult	0.3993	0.3918
Silver Child	0.2866	0.2821
Silver Infant	0.3324	0.3168
Bronze Adult	0.3971	0.3893
Bronze Child	0.2836	0.2789
Bronze Infant	0.3323	0.3165
Catastrophic Adult	0.3975	0.3898
Catastrophic Child	0.2839	0.2792
Catastrophic Infant	0.3326	0.3168

g. Overview of the Payment Transfer Formula (§ 153.320)

In order to maintain the balance of payments and charges that net to zero within each State market, we propose to account for high-cost enrollees through transfer terms (a payment term and a charge term) that would be calculated separately from the State transfer formula. Thus, the non-outlier pooling portion of plan risk will continue to be calculated as the member month-weighted average of individual enrollee risk scores. We previously defined the calculation of plan average actuarial risk and the calculation of payments and charges in the Premium Stabilization Rule. In the 2014 Payment Notice, we combined those concepts into a risk adjustment payment transfer formula. Risk adjustment transfers (total payments and charges including outlier pooling) will be calculated after issuers have completed risk adjustment data reporting. The payment transfer formula includes a set of cost adjustment terms that require transfers to be calculated at the geographic rating area level for each plan (that is, HHS will calculate two separate transfer amounts for a plan that operates in two rating areas).

The payment transfer formula is designed to provide a per member per month (PMPM) transfer amount. The PMPM transfer amount derived from the payment transfer formula would be multiplied by each plan's total member months for the benefit year to determine the total payment due or charge owed by the issuer for that plan in a rating area.

The total payment or charge is thus calculated to balance the State market risk pool in question. In addition to the total charge collected and payment made for the State market risk pool, we propose to add to the risk adjustment methodology additional transfers that would reflect the payments and charges assessed with respect to the costs of high-risk enrollees. In particular, we would add one term that would reflect 60 percent of costs above $2 million, the proposed threshold for our payments for these enrollees, and another term that would reflect a percentage of PMPM premium adjustment to the transfer formula for the high-cost enrollee pool to maintain the balance of payment and charges within the risk adjustment program. We seek comment on this approach to balance transfers between high and low risk plans.

We received feedback in the 2017 Payment Notice and the White Paper from commenters who believe that the inclusion of administrative costs in the Statewide average premium incorrectly increases risk adjustment transfers based on costs that are unrelated to the risk of the enrollee population. Comments ranged from requesting that administrative expenses be removed entirely from the Statewide average premium to requesting that HHS consider basing risk adjustment transfers on a portion of Statewide average premium—namely, the portion representing the sum of claims, claims adjustment expenses, and taxes that are calculated on premiums after risk adjustment transfers by using a specified percentage of Statewide average premiums. While commenters have stated that the inclusion of administrative costs in the Statewide average premium harms efficient plans, we note that low cost plans do not necessarily indicate efficient plans. Should a plan be low cost with low claims costs, it is likely an indication of mispricing, as the issuer should be pricing for average risk. However, we recognize that commenters are concerned that including fixed administrative costs in the Statewide average premium may increase risk adjustment transfers for all issuers based on a percentage of costs that are not dependent on enrollee risk. We have considered some of the potential effects of excluding certain fixed administrative costs from the Statewide average premium. This modification to the treatment of administrative costs in the Statewide average premium would lower absolute risk adjustment transfers for all issuers by an equal percentage. We also note that administrative costs are affected by claims costs and that correctly measuring the portion of administrative costs unaffected by claims costs may be difficult. An incorrect measurement of administrative costs could then result in plans with high risk enrollees being undercompensated. We are continuing to evaluate the impact of administrative expenses on risk adjustment transfers, and seek comment on removing a portion of administrative expenses from the Statewide average premium for the 2018 benefit year or for future benefit years.

i. The Payment Transfer Formula

The payment transfer formula is unchanged from what was finalized in the 2014 Payment Notice (78 FR 15430 through 15434). We believe it useful to republish the formula in its entirety, since, as noted above, we are proposing to recalibrate the HHS risk adjustment model. Transfers (payments and charges) will be calculated as the difference between the plan premium estimate reflecting risk selection and the plan premium estimate not reflecting risk selection. As finalized in the 2014 Payment Notice, the HHS risk adjustment payment transfer formula is:

$$T_i = \left[\frac{PLRS_i \cdot IDF_i \cdot GCF_i}{\sum_i(s_i \cdot PLRS_i \cdot IDF_i \cdot GCF_i)} - \frac{AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i}{\sum_i(s_i \cdot AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i)}\right]\overline{P}_s$$

Where:

$\overline{P}_S$ = State average premium;
$PLRS_i$ = plan *i's* plan liability risk score;
AV_i = plan *i's* metal level AV;
ARF_i = allowable rating factor;
IDF_i = plan *i's* induced demand factor;
GCF_i = plan *i's* geographic cost factor;
s_i = plan *i's* share of State enrollment.

The denominator is summed across all plans in the risk pool in the market in the State.

The difference between the two premium estimates in the payment transfer formula determines whether a plan pays a risk adjustment charge or receives a risk adjustment payment. Note that the value of the plan average risk score by itself does not determine whether a plan would be assessed a charge or receive a payment—even if the risk score is greater than 1.0, it is possible that the plan would be assessed a charge if the premium compensation that the plan may receive through its rating (as measured through the allowable rating factor) exceeds the plan's predicted liability associated with risk selection. Risk adjustment transfers are calculated at the risk pool level, and catastrophic plans are treated as a separate risk pool for purposes of risk adjustment.

This existing formula would be multiplied by the number of member months to determine the total payment or charge assessed with respect to plan average risk scores for a plan's geographic rating area for the market for the State and this payment or charge will be added to the transfer terms described above to account for the costs of high-risk enrollees.

h. Risk Adjustment Issuer Data Requirements (§ 153.610)

In the 2014 Payment Notice, HHS established an approach for obtaining the necessary data for reinsurance and risk adjustment calculations through a distributed data collection model that prevented the transfer of individuals' protected health information. Under § 153.700, each issuer must establish an EDGE server through which it provides HHS access to enrollment, claims, and encounter data. To safeguard enrollees' privacy, each issuer must establish a unique masked enrollee identification number for each enrollee, and may not include personally identifiable information in such masked enrollee identification number. Under the EDGE server approach issuers currently provide plan-level data to HHS.

The lack of enrollee-level data under this approach limits HHS's ability to use that enrollee-level data from risk adjustment covered plans to improve the risk adjustment model recalibration. As we discussed in the White Paper, access to enrollee-level data with masked enrollee IDs would permit HHS to recalibrate the risk adjustment model using actual data from issuers' individual and small group populations, as opposed to the MarketScan® commercial database that approximates individual and small group market populations, while continuing to safeguard the privacy and security of protected health information. Therefore, beginning for the 2019 benefit year, while maintaining the underlying goals of the distributed data approach, including information privacy and security, we propose to recalibrate the risk adjustment model using masked, enrollee-level EDGE server data from the 2016 benefit year. A separate report would be run on issuers' EDGE servers to access select data elements in the enrollee, medical claim, pharmacy claim and supplemental diagnosis files, with masked enrollee ID, plan/issuer ID, rating area, and State. This approach would allow for the creation of a masked, enrollee-level dataset and would not permit HHS to know the identity of the enrollee, the plan ID, the issuer ID, rating area, State or the EDGE server from which the data was extracted. HHS would provide additional information regarding the data elements it would collect and the related process considerations in future guidance.

HHS would use the enrollee-level dataset to recalibrate the risk adjustment model and inform development of the Actuarial Value Calculator and Methodology, which HHS releases annually, to describe how issuers of non-grandfathered health plans in the individual and small group markets are to calculate actuarial value for purposes of determining metal levels. We believe this data could prove a valuable source for calibrating other HHS programs in the individual and small group markets, and that a public use file derived from these data could be a valuable tool for governmental entities and independent researchers to better understand these markets.

We believe that the proposal described above, which minimizes the burden from the issuer by only requiring issuers to execute a new EDGE command for the report to be run on issuers' EDGE servers, permits important improvements to the HHS-operated risk adjustment program while continuing to safeguard privacy and security. We request comment on this proposal.

i. Risk Adjustment User Fee (§ 153.610(f))

As noted above, if a State is not approved to operate or chooses to forgo operating its own risk adjustment program, HHS will operate risk adjustment on the State's behalf. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of States is funded through a risk adjustment user fee. Section 153.610(f)(2) provides that an issuer of a risk adjustment covered plan, as defined in § 153.20, must remit a user fee to HHS equal to the product of its monthly enrollment in the plan and the per enrollee per month risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

To promote operational efficiency, we propose to amend § 153.610(f)(2) to revise the calculation of the risk adjustment user fee to be equal to the product of an issuer's billable monthly enrollment (billable member months) and the per enrollee per month risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters. Billable member months exclude children who do not count toward family rates or family policy premiums.[34] This revision to base the total user fee on billable member months rather than enrollment member months ensures consistency with calculating user fees based on premium revenue generated by issuers, which aligns with the FFE user fee policy. We note that this change would not affect the PMPM risk adjustment user fee rate due to the small relative difference between billable member months and enrollee member months. Therefore, we propose to implement this change beginning for the 2016 benefit year risk adjustment user fee collection, which will be collected in 2017, maintaining the user fee rate set in the 2016 and 2017 Payment Notices. We seek comment on this proposal.

OMB Circular No. A–25R establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. The risk adjustment program will provide special benefits as defined in section 6(a)(1)(b) of Circular No. A–25R to issuers of risk adjustment covered plans because it will mitigate the financial instability associated with potential adverse risk selection. The risk adjustment program will also contribute to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual and small group health insurance markets.

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[34] 78 FR 15432.

In the 2017 Payment Notice, we estimated Federal administrative expenses of operating the risk adjustment program to be $1.56 per enrollee per year, or $0.13 PMPM, based on our estimated contract costs for risk adjustment operations. For the 2018 benefit year, we propose to use the same methodology to estimate our administrative expenses to operate the program. These contracts cover development of the model and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, and operational support. To calculate the user fee, we divide HHS's projected total costs for administering the risk adjustment programs on behalf of States by the expected number of billable member months in risk adjustment covered plans (other than plans not subject to market reforms and student health plans, which are not subject to payments and charges under the risk adjustment methodology HHS uses when it operates risk adjustment on behalf of a State) in HHS-operated risk adjustment programs for the benefit year.

We estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for the 2018 benefit year will be approximately $35 million, and that the risk adjustment user fee would be $1.32 per billable enrollee per year (assuming we finalize our proposal to assess these costs by billable member months discussed above), or $0.12 PMPM. The risk adjustment user fee contract costs for 2018 include costs related to 2018 risk adjustment data validation, and are higher than the 2017 contract costs because some contracts were modified and rebid. However, because enrollment is estimated to be higher in 2018 than 2017, the PMPM amount is lower than that finalized for the 2017 benefit year. We seek comment on this proposal.

j. Data Validation Requirements When HHS Operates Risk Adjustment (§ 153.630)

HHS will conduct risk adjustment data validation in any State where HHS is operating risk adjustment on a State's behalf under § 153.630. The purpose of risk adjustment data validation is to ensure issuers are providing accurate high-quality information to HHS, which is crucial for the proper functioning of the risk adjustment program. Risk adjustment data validation consists of an initial validation audit and a second validation audit. Under § 153.630, each issuer of a risk adjustment covered plan must engage an independent initial validation audit entity. The issuer provides demographic, enrollment, and medical record documentation for a sample of enrollees selected by HHS to its initial validation audit entity for data validation.

i. Materiality Threshold for Risk Adjustment Data Validation

HHS has been evaluating the burden associated with the risk adjustment data validation program, particularly considering the fixed costs associated with hiring an initial validation audit entity and submitting results to HHS, which may be a large portion of some issuers' administrative costs. Beginning for the 2017 benefit year risk adjustment data validation program, HHS is proposing to implement a materiality threshold. This would mean that issuers that fall below a certain threshold would not be required to conduct risk adjustment data validation each year and would instead be subject to random and targeted sampling. We would expect the random sampling to include issuers below the threshold being subject to an initial validation audit approximately every 3 years, barring any risk-based triggers that would warrant annual participation. Potential risk-based metrics we are considering using to select issuers at or below this threshold for more frequent initial validation audits include the issuer's prior risk adjustment data validation results, and material changes in risk adjustment data submission, as measured by our quality metrics. We are proposing to use a threshold of total premiums of $15 million—a threshold at which 1 percent of an issuer's premiums would cover the estimated $150,000 cost of the initial validation audit. Issuers at or below this threshold would not be subject to annual initial validation audit requirements. We estimate that issuers above this threshold represent risk adjustment covered plans that cover approximately 98.5 percent of membership nationally and as such, annual audit of issuers at or below the threshold is not material for purposes of risk adjustment data validation. We seek comment on this proposal, including with respect to the appropriate threshold and the risk-based metrics we should use.

Because risk adjustment data validation error rates are applied to the subsequent year's data, we are considering whether to base the participation requirement metric on the benefit year or the subsequent benefit year. On the one hand, risk adjustment data validation is measuring the accuracy of risk scores from the benefit year. On the other hand, risk adjustment data validation results directly adjust the risk adjustment transfers of issuers participating in risk adjustment in the following benefit year. We note that, even if an issuer is exempt from initial validation audit requirements using the proposed materiality threshold, HHS may require issuers to make records available for review or to comply with an audit by the Federal government under § 153.620. We seek comment on this approach.

We propose that issuers not materially affecting risk adjustment data validation that are not required to perform an initial validation audit would still have their payments adjusted based on an error rate. We are considering an error rate for an issuer not subject to an initial validation audit in a particular year that could be the average negative error rate nationally, or the average negative error rate within a State, or its error rate in past audits. We seek comment on this approach.

ii. Inclusion of Pharmacy Claims in Risk Adjustment Data Validation

Beginning with the 2018 benefit year, as discussed above, the proposed HHS risk adjustment methodology would take into account prescription drug utilization for purposes of determining an enrollee's risk score. HHS proposes to use a hybrid model that employs prescription drug data to supplement diagnostic data by serving as a proxy for a missing diagnosis in cases where diagnostic data are likely to be incomplete and as an indicator of the severity of an enrollee's illness. We propose to require that, with respect to validation of prescription drug utilization of sampled enrollees, an issuer must provide an initial validation audit entity all paid pharmacy claims for an enrollee, against which the initial validation audit entity will validate the associated prescription drug class in the HHS risk adjustment methodology and the impact on the enrollee's risk score.

Therefore, we propose to amend the first sentence of § 153.630(b)(7)(ii) to include enrollees' paid pharmacy claims.

iii. Risk Adjustment Data Validation Discrepancy and Administrative Appeals Process

Under § 153.630(d), an issuer may appeal the findings of a second validation audit or the application of a risk score error rate to its risk adjustment payments and charges. In the 2015 Payment Notice, we stated that we would "provide additional guidance on the appeals process and schedule in future rulemaking." [35] As we noted in the 2015 Payment Notice, HHS will not permit an issuer to appeal the results of the initial validation audit, as the initial validation audit entity is under contract with the issuer and HHS does not produce the initial validation audit results. We are proposing to amend § 153.630(d) to clarify that an issuer may appeal the findings of a second validation audit or the calculation of a risk score error rate. We make this clarification to distinguish the calculation of a risk score error rate from the application of a risk score error rate as the calculation is a separate reason for which an issuer could appeal. We further propose to clarify that if an issuer intends to appeal the application of a risk score error rate to its risk adjustment payments and charges, HHS would deem this a risk adjustment payment or charge amount appeal under § 156.1220(a)(1)(ii). In this proposed rule, we also propose an interim and final discrepancy reporting process for the risk adjustment data validation program and we propose codification of the process by which an issuer may file an appeal of the findings of a second validation audit or the calculation of a risk score error rate.

First, we propose an interim discrepancy reporting process by which an issuer must confirm the risk adjustment data validation initial audit sample provided by HHS under § 153.630(b)(1) or file a discrepancy report. We propose amending § 153.630 by removing the introductory language and adding paragraph (d)(1) to provide that in the manner set forth by HHS, within 15 calendar days of notification of the initial validation audit sample set forth by HHS, an issuer must confirm the sample or file a discrepancy report to dispute the HHS risk adjustment data validation initial validation audit sample set forth by HHS. In light of the timing of this interim discrepancy reporting process, we do not propose to permit issuers to appeal the resolution of any interim discrepancy disputing the sample. We believe that providing an interim administrative appeals process or permitting issuers to appeal the HHS risk adjustment data validation initial validation audit sample after completion of the entire risk adjustment data validation process for a benefit year would delay the HHS risk adjustment data validation process. Additionally, we believe that it could be efficient to resolve any issues related to the risk adjustment data validation initial audit sample provided by HHS under § 153.630(b)(1) during an interim discrepancy reporting process. We propose to require confirmation of the sample, in the form of an attestation, in order to ensure that issuers thoroughly review the initial validation audit sample determined by HHS.

Second, we propose a final, formal discrepancy reporting process, by which an issuer must confirm the findings of the second validation audit or the calculation of a risk score error rate, or notify us if the issuer identifies a discrepancy with the findings of a second validation audit or the calculation of a risk score error rate. We propose adding paragraph (d)(2) to § 153.630 to provide that in the manner set forth by HHS, an issuer must attest to or report a discrepancy within 15 calendar days of notification of the findings of a second validation audit or the calculation of a risk score error rate to dispute the findings of a second validation audit or the calculation of a risk score error rate. We believe this discrepancy reporting process will enable HHS to work with issuers to resolve discrepancies prior to the notification or risk adjustment payments or charges due under § 153.310(e) and application of the risk score error rate to the issuer's risk adjustment payments and charges.

As we will discuss in further detail in the preamble to § 156.1220(a), we also propose requiring issuers to report a discrepancy if the issue is identifiable prior to filing a request for reconsideration as set forth in 45 CFR 156.1220. As such, we propose to amend § 156.1220(a)(4)(ii), to provide that notwithstanding § 156.1220(a)(1), a reconsideration with respect to a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error may be requested only if, to the extent the issue could have been previously identified by the issuer to HHS under § 153.630(d)(2) or § 153.710(d)(2), it was so identified and remains unresolved.

Third, we propose to amend § 153.630 to add paragraph (d)(3) to clarify the process by which an issuer can appeal the findings of a second validation audit or the calculation of a risk score error rate. We propose requiring issuers to use the administrative appeals process set forth in § 156.1220. We believe issuers will appreciate a discrepancy reporting window and leveraging the existing administrative appeals processes.

HHS will provide in future guidance the process for issuers to report discrepancies. We believe that providing issuers 15 calendar days to review the HHS risk adjustment data validation sample set, will provide adequate time for issuers to notify HHS prior to the execution of the initial validation audit. Additionally, we believe providing issuers 30 calendar days from the results of the second validation audit or the calculation of a risk score error rate based on risk adjustment data validation, will provide adequate time for issuers to notify HHS prior to filing a formal request for reconsideration of such discrepancy. As with the discrepancy reporting process set forth in § 153.710(d), HHS will work with issuers to resolve any discrepancies related to risk adjustment data validation prior to final risk adjustment payments and charges for a benefit year. We seek comment on these timeframes and these discrepancy reporting and appeal proposals.

G. Part 154—Health Insurance Issuer Rate Increases: Disclosure and Review Requirements

1. Definitions (§ 154.102)

We propose to revise the definition of "product" in § 154.102. Specifically, we propose to remove language that would restrict a product's being considered the same product when it is no longer offered by the same issuer, but by a different issuer in the same controlled group. This amendment is necessary in light of our proposed interpretation of guaranteed renewability provisions, as discussed in the preamble to § 147.106. We are not proposing changes to the definition of "plan" because the definition for that term in § 154.102 cross-references the definition in § 144.103. Therefore, if finalized as proposed, the amendments to the definition of "plan" in § 144.103 would also apply for purposes of the rate review requirements under 45 CFR part 154. For further discussion of the reason for this proposed amendment, please see the preamble to § 147.106.

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[35] HHS Notice of Benefit and Payment Parameters for 2015, 79 FR 13768

H. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. Standardized Options (§ 155.20)

a. Standardized Options Approach for 2018

In the 2017 Payment Notice, HHS finalized six standardized options (also now referred to as Simple Choice plans), one at each of the bronze, silver, silver cost-sharing reduction variation, and gold levels of coverage, designed to be similar to the most popular (enrollment-weighted) QHPs in the 2015 individual market FFEs. We propose to change the standardized options from the 2017 versions in order to reflect changes in QHP enrollment-weighted data from 2015 to 2016, including SBE–FP QHP enrollment-weighted data, and to the extent practicable, to comply with various State cost-sharing standards. Therefore, for the 2018 plan year, HHS proposes three new sets of standardized options, based on an analysis of enrollment-weighted 2016 individual market FFE and SBE–FP QHPs (see Tables 12, 13 and 14). The second and third sets are different from the first set only to the extent necessary to comply with State cost-sharing laws. The second set of standardized options is designed to work in States that: (1) Require that cost sharing for physical therapy, occupational therapy, or speech therapy be no greater than the cost sharing for primary care visits; (2) limit the amount that can be charged for each drug tier; or (3) require that all drug tiers carry a copayment rather than coinsurance. The third set of standardized options is designed to work in a State with maximum deductible requirements and other cost-sharing standards.

Like the 2017 standardized options, the proposed 2018 standardized options each have a single provider tier, fixed deductible, fixed annual limitation on cost sharing, and fixed copayment or coinsurance for a key set of essential health benefits that comprise a large percentage of the total allowed costs for a typical population of enrollees. These fixed cost-sharing values are for in-network care only. Unlike the 2017 standardized options, the proposed 2018 options at the silver, silver cost-sharing reduction variations, and gold levels of coverage have separate medical and drug deductibles, reflecting the commonality of this cost-sharing structure in QHPs at these levels of coverage. The proposed standardized options at the silver 87 percent cost-sharing reduction plan variation, silver 94 percent cost-sharing reduction plan variation, and gold levels of coverage have a drug deductible equal to $0, meaning no deductible applies to the drugs.

The bronze standardized options as proposed rely on finalization of the proposal discussed in the preamble to § 156.140 to permit a broader de minimis range for bronze plans. If that proposal is not adopted, the plans would be revised to comply with the de minimis range in our regulations, while still reflecting 2016 enrollment weighted data, and State cost-sharing requirements for the second set of standardized options.

For 2018, we also propose a fourth standardized option at the bronze level of coverage that qualifies as a high deductible health plan (HDHP) under section 223 of the Code, eligible for use with a health savings account (HSA). HDHPs are an option valued by many consumers—enrollment in HDHPs across 2016 individual market FFE and SBE–FP QHPs constituted 9.2 percent of all FFE and SBE–FP QHP enrollment in 2016. Pursuant to the terms of the Code, the IRS releases the maximum annual limitation on cost sharing and minimum annual deductible for HDHPs annually in the spring, subsequent to the annual HHS notice of benefit and payment parameters rulemaking process. Therefore, we propose that if any changes to the HDHP standardized option would be required to reflect differences between the HDHP standardized option finalized in the 2018 Payment Notice and the subsequently released maximum annual limitation on cost sharing and minimum annual deductible for HDHPs, HHS would publish those changes in guidance. Accordingly, we propose to amend the definition of "standardized option" at § 155.20 to provide for a plan to be considered a standardized option if it is: (1) A QHP offered for sale through an individual market Exchange with a standardized cost-sharing structure specified by HHS in rulemaking; or (2) an HDHP QHP offered for sale through an individual market Exchange with a standardized cost-sharing structure specified by HHS in guidance issued solely to modify the cost-sharing structure specified by HHS in rulemaking to the extent necessary to align with requirements to qualify as an HDHP under section 223 of the Code and meet HHS AV requirements.

b. Standardized Options in SBE–FPs

In the 2017 Payment Notice, we designed a set of standardized options based on enrollment-weighted 2015 FFE QHP data, and indicated we anticipated differentially displaying these HHS-designed standardized options. We noted that SBE–FPs may have their own State-designed standardized plans that differ from HHS-designed standardized options, but that the *HealthCare.gov* platform would not be able to differentially display these State-designed standardized plans.

For 2018, the *HealthCare.gov* platform remains unable to provide differential display to State-designed standardized plans that differ from the HHS-designed standardized options. However, we propose that SBE–FPs may choose to allow HHS-designed standardized options to receive differential display on *HealthCare.gov*, just as the plans would if offered through an FFE. We propose that an SBE–FP must notify HHS if it wants HHS-designed standardized options to receive differential display by a date to be specified in guidance that will be set to provide sufficient time to operationalize the State's choice on *HealthCare.gov*. We seek comment on this proposal.

c. State Customization

In the 2017 Final Payment Notice, HHS explained that it would not be possible for *HealthCare.gov* to accommodate customization of standardized options by State in 2017. Specifically, to reduce operational complexity, HHS did not vary the standardized options by State or by region, and instead finalized one set of standardized options across all FFEs that issuers would have the option to offer in 2017.

As noted above, some States regulate cost sharing on specific benefits under State authorities. We seek to accommodate, to the extent practicable, State cost-sharing requirements under our proposed 2018 standardized options. To do so, we have designed three bronze standardized options (in addition to the bronze HDHP), and three standardized options at each of the silver, silver cost-sharing reduction plan variations, and gold levels of coverage, as set forth in Tables 13 and 14. We propose to select for each FFE State one of the three standardized options at each level of coverage (plus the HDHP option at the bronze level, if permissible under State cost-sharing standards) that meets any existing State cost-sharing requirements. We propose that this selection will be published in the final 2018 Payment Notice. We propose to do the same for each SBE–FP State that notifies HHS that it chooses to have HHS standardized options receive differential display on the *HealthCare.gov* platform. If issuers in the FFE States and those in the SBE–FP States that choose to have differential display of HHS standardized options offer the standardized options selected for the State (that is, the one standardized option at each level of coverage selected for the State, in addition to the HDHP option if permissible under State standards), those plans would receive differential display in the Exchange for the 2018 plan year.

Additionally, many States have oral chemotherapy access laws, which require coverage of oral chemotherapy at parity with intravenous chemotherapy or cap patients' monthly cost sharing for chemotherapy drugs (both oral and intravenous). We propose to clarify that these chemotherapy access requirements do not conflict with the HHS standardized plan designs because issuers can design benefit packages that comply with both the standardized options requirements and State oral chemotherapy access laws.

We believe that the proposals discussed above will allow issuers in States with cost-sharing laws that would conflict with a single set of standardized options to offer standardized options. Furthermore, by making it possible for issuers to offer standardized options while complying with State cost-sharing rules, we believe this limited State customization will enhance the shopping experience of consumers in more States than was previously possible. We welcome comments from each State regarding the standardized option at each level of coverage that the State believes would be most suitable for that State, and whether modifications should be made to any of the proposed State-customized standardized options to further accommodate State cost-sharing rules. We also seek comment from States, issuers, and other stakeholders on State cost-sharing requirements that would affect the design of standardized options, as well as comments generally on this approach for standardized options in 2018.

TABLE 12—2018 PROPOSED STANDARDIZED OPTIONS

	Bronze	HSA-eligible bronze HDHP	Silver	Silver 73% CSR plan variation	Silver 87% CSR plan variation	Silver 94% CSR plan variation	Gold
Actuarial Value (%)	62.68%	61.97%	71.05%	73.95%	87.61	94.69	80.65%.
Deductible (Med/Rx)	$6,650	$6,000	$3,500/$500	$3,000/$200	$700/$0	$250/$0	$1,400/$0.
Annual Limitation on Cost Sharing.	$7,350	$6,000	$7,350	$5,850	$2,450	$1,250	$5,000.
Emergency Room Services.	40%	No charge after deductible.	20%	20%	20%	5%	20%.
Urgent Care	$75 (*)	No charge after deductible.	$75 (*)	$75 (*)	$40 (*)	$25 (*)	$60 (*).
Inpatient Hospital Services	40%	No charge after deductible.	20%	20%	20%	5%	20%.
Primary Care Visit	$35 (*)	No charge after deductible.	$30 (*)	$30 (*)	$10 (*)	$5 (*)	$20 (*).
Specialist Visit	$75 (*)	No charge after deductible.	$65 (*)	$65 (*)	$25 (*)	$10 (*)	$50 (*).
Mental Health/Substance Use Disorder Outpatient Office Visit.	$35 (*)	No charge after deductible.	$30 (*)	$30 (*)	$10 (*)	$5 (*)	$20 (*).
Imaging (CT/PET Scans, MRIs).	40%	No charge after deductible.	20%	20%	20%	5%	20%.
Speech Therapy	40%	No charge after deductible.	20%	20%	20%	5%	20%.
Occupational Therapy/ Physical Therapy.	40%	No charge after deductible.	20%	20%	20%	5%	20%.
Laboratory Services	40%	No charge after deductible.	20%	20%	20%	5%	20%.
X-rays and Diagnostic Imaging**.	40%	No charge after deductible.	20%	20%	20%	5%	20%.
Skilled Nursing Facility	40%	No charge after deductible.	20%	20%	20%	5%	20%.
Outpatient Facility Fee (for example, Ambulatory Surgery Center).	40%	No charge after deductible.	20%	20%	20%	5%	20%.
Outpatient Surgery Physician/Surgical Services.	40%	No charge after deductible.	20%	20%	20%	5%	20%.
Generic Drugs	$35 (*)	No charge after deductible.	$15 (*)	$15 (*)	$5 (*)	$3 (*)	$10 (*).
Preferred Brand Drugs	35%	No charge after deductible.	$50 (*)	$50 (*)	$25 (*)	$5 (*)	$40 (*).
Non-Preferred Brand Drugs.	40%	No charge after deductible.	$100 (*)	$100 (*)	$50 (*)	$10 (*)	$75 (*).
Specialty Drugs	45%	No charge after deductible.	40%	40%	30%	25%	30%.

(*) = not subject to the deductible
** **Note:** Excludes x-rays and diagnostic imaging associated with office visits (except for high-deductible health plans (HDHPs).

Table 13—2018 Proposed Standardized Options for States Requiring Occupational Therapy, Physical Therapy, or Speech Therapy Cost-Sharing Parity with Primary Care Visits or States Requiring Copayments or Copayment Limits on Drugs

	Bronze	Silver	Silver 73% CSR plan variation	Silver 87% CSR plan variation	Silver 94% CSR plan variation	Gold
Actuarial Value (%)	62.79%	71.03%	73.88%	87.70	94.68	80.60%.
Deductible (Med/Rx)	$6,650	$3,500/$500 Rx	$3,000/$200 Rx	$700/$0	$250/$0	$1,400/$0.
Annual Limitation on Cost Sharing.	$7,350	$7,350	$5,850	$2,450	$1,250	$5,000.
Emergency Room Services.	40%	20%	20%	20%	5%	20%.
Urgent Care	$75 (*)	$75 (*)	$75 (*)	$40 (*)	$25 (*)	$60 (*).
Inpatient Hospital Services.	40%	20%	20%	20%	5%	20%.
Primary Care Visit	$35 (*)	$30 (*)	$30 (*)	$10 (*)	$5 (*)	$20 (*).
Specialist Visit	$75 (*)	$65 (*)	$65 (*)	$25 (*)	$10 (*)	$50 (*).
Mental Health/Substance Use Disorder Outpatient Office Visit.	$35 (*)	$30 (*)	$30 (*)	$10 (*)	$5 (*)	$20 (*).
Imaging (CT/PET Scans, MRIs).	40%	20%	20%	20%	5%	20%.
Speech Therapy	$35 (*)	$30 (*)	$30 (*)	$10 (*)	$5 (*)	$20 (*).
Occupational Therapy/Physical Therapy.	$35 (*)	$30 (*)	$30 (*)	$10 (*)	$5 (*)	$20 (*).
Laboratory Services	40%	20%	20%	20%	5%	20%.
X-rays and Diagnostic Imaging**.	40%	20%	20%	20%	5%	20%.
Skilled Nursing Facility	40%	20%	20%	20%	5%	20%.
Outpatient Facility Fee (e.g., Ambulatory Surgery Center).	40%	20%	20%	20%	5%	20%.
Outpatient Surgery Physician/Surgical Services.	40%	20%	20%	20%	5%	20%.
Generic Drugs	$35 (*)	$15 (*)	$15 (*)	$5 (*)	$3 (*)	$10 (*).
Preferred Brand Drugs	$40 (copay applies only after deductible).	$50 (*)	$50 (*)	$25 (*)	$5 (*)	$40 (*).
Non-Preferred Brand Drugs.	$45 (copay applies only after deductible).	$100 (*)	$100 (*)	$50 (*)	$10 (*)	$75 (*).
Specialty Drugs	$50 (copay applies only after deductible).	$150 (copay applies only after deductible).	$150 (copay applies only after deductible).	$75 (*)	$20 (*)	$100(*).

(*) = not subject to the deductible.
Note: Excludes x-rays and diagnostic imaging associated with office visits.

Table 14—2018 Proposed Standardized Options for States with Deductible Maximums and Other Cost-Sharing Requirements

	Bronze	Silver	Silver 73% CSR plan variation	Silver 87% CSR plan variation	Silver 94% CSR plan variation	Gold
Actuarial Value (%)	64.84%	70.28%	73.94%	87.61%	94.53%	80.80%.
Deductible	$3,000	$3,000	$3,000	$700	$250	$1,000.
Annual Limitation on Cost Sharing	$7,150	$7,000	$5,850	$2,450	$1,250	$5,000.
Emergency Room Services	50%	40%	20%	20%	5%	30%.
Urgent Care	$50 (*)	$50 (*)	$50 (*)	$40 (*)	$25 (*)	$40 (*).
Inpatient Hospital Services	$500 (per day; applies only after deductible).	40%	20%	20%	5%	30%.
Primary Care Visit	$35 (*first 3 visits; then subject to deductible and $35 copay after deductible).	$30 (*)	$30 (*)	$10 (*)	$5 (*)	$25 (*).
Specialist Visit	$75 (applies only after deductible).	$60 (*)	$60 (*)	$25 (*)	$10 (*)	$40 (*).
Mental Health/Substance Use Disorder Outpatient Office Visit.	$35 (applies only after deductible).	$30 (*)	$30 (*)	$10 (*)	$5 (*)	$25 (*).
Imaging (CT/PET Scans, MRIs)	$100 (applies only after deductible).	$100 (*)	$100 (*)	$75 (*)	$40 (*)	$100 (*).
Speech Therapy	$35 (applies only after deductible).	$50 (*)	$30 (*)	$10 (*)	$5 (*)	$25 (*).
Occupational Therapy/Physical Therapy.	$35 (applies only after deductible).	$50 (*)	$30 (*)	$10 (*)	$5 (*)	$25 (*).

Table 14—2018 Proposed Standardized Options for States with Deductible Maximums and Other Cost-Sharing Requirements—Continued

	Bronze	Silver	Silver 73% CSR plan variation	Silver 87% CSR plan variation	Silver 94% CSR plan variation	Gold
Laboratory Services	50%	40%	20%	20%	5%	30%.
X-rays and Diagnostic Imaging**	50%	40%	20%	20%	5%	30%.
Skilled Nursing Facility	$500 (per day; applies only after deductible).	40%	20%	20%	5%	30%.
Outpatient Facility Fee (e.g., Ambulatory Surgery Center).	50%	40%	20%	20%	5%	30%.
Outpatient Surgery Physician/Surgical Services.	50%	40%	20%	20%	5%	30%.
Generic Drugs	$25 (*)	$25 (*)	$15 (*)	$5 (*)	$3 (*)	$10 (*).
Preferred Brand Drugs	50%	$75 (*)	$75 (*)	$25 (*)	$5 (*)	$25 (*).
Non-Preferred Brand Drugs	50%	$75 (*)	$75 (*)	$50 (*)	$10 (*)	$50 (*).
Specialty Drugs	50%	$75 (*)	$75 (*)	$50 (*)	$10 (*)	$50 (*).

(*) = not subject to the deductible
** Note: Excludes x-rays and diagnostic imaging associated with office visits.

2. General Functions of an Exchange

a. Functions of an Exchange (§ 155.200)

In the 2017 Payment Notice, we established that a State Exchange could elect to enter into a Federal platform agreement through which it agrees to rely on HHS for services related to the individual market Exchange, the SHOP Exchange, or both. In § 155.200(f)(2), we required an SBE–FP to establish and oversee certain requirements for its QHPs and QHP issuers that are no less strict than the requirements that apply to QHPs and QHP issuers in an FFE. Requiring QHPs and QHP issuers in SBE–FPs to meet these same requirements ensures that all QHPs on HealthCare.gov meet a consistent minimum standard and that consumers obtaining coverage as a result of applying through HealthCare.gov are guaranteed plans that meet these minimum standards.

We propose to amend § 155.200(f) by adding a new paragraph (f)(4) that would require State Exchanges that use the Federal platform for certain SHOP functions to establish standards and policies consistent with certain Federally-facilitated Small Business Health Options Program (FF–SHOP) requirements. In contrast to the requirements contained in § 155.200(f)(2), which pertain primarily to ensuring a consistent experience on *HealthCare.gov,* compliance with the requirements we propose to include in § 155.200(f)(4) would be necessary because the FF–SHOP requirements listed in paragraph (f)(4) are an integral part of the FF–SHOP platform's functionality and system build, making compliance with the requirements necessary from an operational perspective for State Exchanges to use the Federal platform for these SHOP functions. Additionally, requiring compliance with these requirements, rather than customizing the FF–SHOP platform's system build, would avoid sizeable costs associated with permitting State-based Exchanges to use the Federal platform for SHOP functions. Therefore, we propose to add a new paragraph (f)(4) to require that SBE–FPs that utilize the Federal platform for certain SHOP functions establish standards and policies with respect to the following topics that are consistent with the following rules applicable in FF–SHOPs:

- Premium calculation, payment, and collection requirements as specified at § 155.705(b)(4) (for SBE–FPs using the Federal platform for SHOP eligibility, enrollment, or premium aggregation functions);
- The timeline for rate changes set forth at § 155.705(b)(6)(i)(A) (for SBE–FPs using the Federal platform for SHOP enrollment or premium aggregation functions);
- Minimum participation rate requirements and calculation methodologies set forth at § 155.705(b)(10) (for SBE–FPs using the Federal platform for SHOP enrollment functions);
- Employer contribution methodologies set forth at § 155.705(b)(11)(ii) (for SBE–FPs using the Federal platform for SHOP enrollment or premium aggregation functions);
- Annual employee open enrollment period requirements set forth at § 155.725(e)(2) (for SBE–FPs using the Federal platform for SHOP enrollment functions);
- Initial group enrollment or renewal coverage effective date requirements set forth at § 155.725(h)(2) (for SBE–FPs using the Federal platform for SHOP enrollment functions); and
- Termination of SHOP coverage or enrollment rules set forth at § 155.735 (for SBE–FPs using the Federal platform for SHOP eligibility, enrollment, or premium aggregation functions).

These amendments would become effective with the effective date of the final rule.

We seek comment on this proposal, including on whether it would conflict with current State requirements, and on whether other FF–SHOP requirements should apply in SBE–FPs utilizing the Federal platform for SHOP functions, for the reasons discussed above.

b. Consumer Assistance Tools and Programs of an Exchange (§ 155.205)

Section 155.205(c)(2)(iii)(A) and (B) require Exchanges, QHP issuers, and agents or brokers subject to § 155.220(c)(3)(i) ("web-brokers") to provide taglines in non-English languages indicating the availability of language services. These entities must include taglines on Web site content and documents that are critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. The taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient (LEP) population of the relevant State, as determined in HHS guidance. In March 2016, HHS issued guidance providing language data and sample taglines in the top 15 languages spoken by the LEP population in each State.[36] A similar tagline requirement

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[36] Ctr. Consumer Info. & Ins. Oversight, Ctrs. for Medicaid & Medicare Serv., Guidance and

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appears in the final rule implementing section 1557 of the Affordable Care Act (81 FR 31376 (May 18, 2016)), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities.[37] The section 1557 implementing regulation applies to every health program or activity administered by an Exchange, every health program or activity administered by HHS, and every health program or activity, any part of which receives Federal financial assistance provided or made available by HHS.[38] The section 1557 implementing regulation, as well as other applicable Federal civil rights laws, apply independently of the regulations governing Exchanges and health insurance issuers.

In the preamble to the 2016 Payment Notice, we stated that if an entity's service area covers multiple States, the top 15 languages spoken by LEP individuals may be determined by aggregating the top 15 languages spoken by all LEP individuals among the total population of the relevant States (80 FR 10788). We also restated this policy in the March 2016 guidance. We propose to amend § 155.205(c)(2)(iii) to provide more specificity about when entities subject to § 155.205(c)(2)(iii)(A) and (B) would be permitted to aggregate LEP populations across States to determine the languages in which taglines must be provided, in light of questions that have arisen about this issue since publication of the 2016 Payment Notice.

At § 155.205(c)(2)(iii)(A), we propose that if an Exchange is operated by an entity operating multiple Exchanges, or relies on an eligibility or enrollment platform that is relied on by multiple Exchanges, the Exchange may aggregate the LEP populations across all the States served by the entity that operates the Exchange or its eligibility or enrollment platform to determine the top 15 languages required for taglines under § 155.205(c)(2)(iii)(A). For example, under this proposal, all Exchanges that use the eligibility and enrollment platform on which the FFEs (including FFEs where States perform plan management functions) and SBE–FPs rely would be permitted to aggregate languages across the States with Exchanges that rely on this platform.

At § 155.205(c)(2)(iii)(A), we also propose that a QHP issuer would be permitted to aggregate the LEP populations across all States served by the health insurance issuers within the issuer's controlled group, whether or not those health insurance issuers offer plans through the Exchange in each of those States, to determine the top 15 languages in which it must provide taglines. For consistency, we propose to define an issuer's controlled group using the definition in § 147.106(d)(3)(i) of this proposed rule, which would define a controlled group as a group of two or more persons that is treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Code. Therefore, a QHP issuer that is a subsidiary of a corporate entity or holding company that is treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Code, and whose subsidiary health insurance issuers serve multiple States, would be permitted to meet the tagline requirement by including taglines on Web sites and critical documents in at least the top 15 languages spoken by the aggregated LEP populations of all States served by the corporate entity's or holding company's subsidiary health insurance issuers, rather than in the top 15 languages spoken by the limited English proficient population of each individual QHP issuer's State of licensure or State served. On the other hand, a QHP issuer association or federation comprised of multiple companies that are not treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Code, and are thus not considered to be a controlled group, would not be permitted to aggregate across the States served by the health insurance issuers in its entire association or federation; rather, the QHP issuer members of the association or federation would be permitted to aggregate only across the States served by the health insurance issuers within each issuer's controlled group.

With respect to summaries of benefits and coverage (SBCs) provided under section 2715 of the PHS Act, consistent with the SBC Instruction Guide for Individual Health Insurance Coverage[39] and the SBC Instruction Guide for Group Coverage,[40] QHP issuers would still be required to provide an addendum with their SBCs with language taglines in the top 15 languages spoken by the LEP populations of the relevant State or States for QHPs offered through an Exchange. Any additional taglines required under section 2715 of the PHS Act and the implementing regulations[41] must also be included in this addendum. However, any taglines that are included in the addendum are not required to also be included in the SBC document. The addendum, which must only include tagline information required by the applicable language access standards, must be provided along with the SBC and is not considered a part of the SBC document. Therefore, the addendum will not count towards the four double-sided page limit for the SBC under PHS Act section 2715(b)(1).

Additionally, our proposed policy related to aggregating LEP populations to determine the top 15 languages in which taglines must be provided does not apply to the tagline requirements under rules implementing sections 2715 and 2719 of the PHS Act. This means, for example, that a QHP issuer that is a member of a controlled group whose health insurance issuers serve three States, and that therefore aggregates the LEP populations across those three States to determine the top 15 languages in which it must provide taglines in its SBC addendum under § 155.205(c)(2)(iii)(A), must still include in its SBC addendum taglines in all of the languages triggered by the threshold under § 147.200(a)(5), which requires a tagline when 10 percent or more of the population residing in a county is

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Population Data for Exchanges, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR 155.205(c) and 156.250 (March 30, 2016), *available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Language-access-guidance.pdf*; Appendix A—Top 15 Non-English Languages by State, *available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Appendix-A-Top-15.pdf*; Appendix B—Sample Translated Taglines, *available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Appendix-B-Sample-Translated-Taglines.pdf*.

[37] 42 U.S.C. 18116; 45 CFR part 92. Section 92.8(d)(1) requires each covered entity to "post taglines in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States." The principle of aggregation with respect to the tagline requirement at § 92.8(d)(1) is discussed in the section 1557 final rule at 81 FR 31376, 31400.

[38] 45 CFR 92.2(a). In addition to the tagline requirement at § 92.8(d)(1), the section 1557 implementing regulation identifies other obligations of a covered entity, such as the obligation to have marketing practices and benefit designs in a health-related insurance plan or policy or other health-related coverage that are nondiscriminatory. *See id.* § 92.207.

[39] Summary of Benefits and Coverage: Instruction Guide for Individual Health Insurance Coverage (April 2017), *available at https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Individual-Instructions-508–MM.pdf*.

[40] Summary of Benefits and Coverage: Instruction Guide for Group Coverage (April 2017), *available at https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Group-Instructions-4–4-clean-MM–508.pdf*

[41] 45 CFR 147.200(a)(5) requires that group health plans and health insurance issuers offering group and individual health insurance coverage provide taglines in a particular non-English language if 10 percent or more of the population residing in the county is literate only in that same non-English language.

literate only in a particular non-English language, *without* aggregating the LEP populations across the counties in its service area. The same would apply to tagline requirements under section 2719 of the PHS Act and its implementing regulations.

We also propose amendments to § 155.205(c)(2)(iii)(B), to specify that web-brokers that are licensed in and serving multiple States would be permitted to aggregate the LEP populations in the States they serve to determine the top 15 languages in which they must provide taglines under § 155.205(c)(2)(iii)(B).

We believe our proposed approach balances two important policy objectives: Ensuring that LEP individuals have notice of language assistance services, and minimizing burden on the entities subject to the rule, including by minimizing the potential need for costly information systems changes. This approach would establish a floor, and if it is finalized, QHP issuers, web-brokers, and Exchanges would be permitted to provide non-aggregated, State-specific taglines, or taglines in more than the required 15 languages. We believe our proposed approach would help promote consistency with the tagline requirements at 45 CFR 92.8(d)(1) and 81 FR 31400, which permit covered entities that serve individuals in more than one State to aggregate the number of individuals with limited English proficiency in those States to determine the top 15 languages required by § 92.8(d)(1). We seek comment on whether the proposed approach strikes the appropriate balance.

We are also proposing amendments to § 155.205(c)(2)(iii)(A) and (B) to specify that Exchanges, QHP issuers, and web-brokers may satisfy tagline requirements with respect to Web site content if they post a Web link prominently on their home page that directs individuals to the full text of the taglines indicating how individuals may obtain language assistance services, and if they also include taglines on any standalone document linked to or embedded in the Web site, such as one in portable document format (PDF) or word processing software format, that is critical within the meaning of the rule. Thus, for example, if a QHP issuer included a link to a PDF of its provider directory or formulary drug list on its Web site, it would be required to provide a link to taglines on its Web site home page and to provide taglines on that PDF document. In HHS's view, providing a prominent link to taglines on the home page of a Web site gives sufficient notice to consumers that language services are available. We note that entities subject to section 1557 of the Affordable Care Act are still required to comply with the section 1557 requirements regarding taglines placed on their home pages.[42]

In the case of "critical" standalone documents linked to or embedded in the Web site, there is a good chance that a consumer might land on such documents without going through an entity's home page first (for example, from a link on another Web site), and it is also likely that such documents would not contain a link to the entity's home page. In contrast, Web pages within the Web site that are not standalone linked or embedded documents are more likely to contain a prominent link to the home page. Under this proposal, if an entity subject to § 155.205(c)(2)(iii)(A) or (B) includes the required taglines in a standalone "critical" document linked to or embedded in the Web site of another entity subject to § 155.205(c)(2)(iii)(A) or (B), then the taglines standard will be deemed to be met by the entity that links to or embeds the "critical" document in its Web site, for purposes of that document. For example, if a web-broker posts a "critical" document provided to it by an affiliated QHP issuer, and the QHP issuer includes the taglines in that document that the issuer would be required to include, then the web-broker can rely on those taglines for purposes of compliance with § 155.205(c)(2)(iii)(B) when it posts that document (as provided by the QHP issuer with the required taglines), even if the QHP issuer and web-broker are not required to provide taglines in the same 15 languages.

We solicit comments on all aspects of these proposals. In particular, we seek comments on whether we should consider alternative standards for identifying the States across which Exchanges, QHP issuers, and web-brokers may aggregate languages for purposes of § 155.205(c)(2)(iii)(A) and (B), and on whether our proposed approach strikes an appropriate balance between facilitating access for LEP populations and minimizing burden on the entities subject to the rule.

Additionally, because the final rule implementing section 1557 of the Affordable Care Act (81 FR 31376 (May 18, 2016)) imposes on the covered entities to which that rule applies a similar set of obligations with respect to language access taglines, we are considering whether there is a need for the separate language access tagline requirements for Exchanges, QHP issuers, and web-brokers under § 155.205(c)(2)(iii)(A) and (B). We seek comment on what, if any, additional protections for LEP consumers the standards under § 155.205(c)(2)(iii)(A) and (B) provide that are not included in the section 1557 implementing regulation, and on whether the § 155.205(c)(2)(iii)(A) and (B) requirements are largely duplicative of the section 1557 implementing regulation. We note that not every entity subject to § 155.205(c)(2)(iii)(A) or (B) is a "covered entity" subject to section 1557 and its implementing regulation. We are committed to ensuring that LEP consumers have sufficient notice of language assistance services, while also seeking to minimize the burden on the entities subject to both the section 1557 implementing regulation and Exchange language access requirements, including by minimizing duplicative requirements and the potential need for costly information systems changes. For these reasons, and for continuity with our existing requirements and the principle that LEP consumers should have notice of language access services whether they are being served by an Exchange, QHP issuer, or a web-broker,[43] we are considering amending § 155.205(c)(2)(iii) to replace the tagline requirements currently set forth at § 155.205(c)(2)(iii)(A) and (B) with a provision requiring Exchanges, QHP issuers, and web-brokers to follow certain standards under § 92.8 when providing the taglines required under § 155.205(c)(2)(iii). Under this alternative proposal, to the extent that any entity subject to existing § 155.205(c)(2)(iii)(A) and (B) is not a covered entity within the meaning of section 1557 and its implementing regulation, the standards under § 92.8 would apply as if such entity were a covered entity. We are also considering limiting the cross-reference such that Exchanges, QHP issuers, and web-brokers would have to comply only with the standards related to taglines at § 92.8(d)(1) and (f) when providing the taglines required under § 155.205(c)(2)(iii), and would not have to comply with other notice requirements in § 92.8, such as § 92.8(a). This approach would be similar to our existing regulations and would not require documents to include additional information, such as nondiscrimination disclosures and grievance processes, that are not contemplated by § 155.205(c)(2)(iii)(A) and (B), unless the entity providing taglines is separately subject to § 92.8. Under this alternative proposal, we are also considering retaining the requirement that taglines must be provided on critical documents within the meaning of § 155.205(c)(2)(iii)(A) and (B), rather than applying the requirement at § 92.8(f)(1)(i) related to significant publications and significant communications. However, we seek comment on this approach and on whether describing the types of materials on which taglines must be provided by Exchanges, QHP issuers, and web-brokers by instead referring to significant publications and significant communications at § 92.8(f)(1)(i) would help streamline these requirements for entities subject to § 155.205(c)(2)(iii)(A) and (B). We are also considering removing § 155.205(c)(2)(iii)(A) and (B) entirely. In any case, as noted above, the section 1557 implementing regulation applies independently of the regulations governing Exchanges and health insurance issuers. We request comments on all of these considerations, including with respect to what other conforming changes to § 155.205(c)(2)(iii) or other regulations such as § 156.250 might be advisable in order to implement a policy of relying upon the substantive standards under section 1557 and associated rulemaking and guidance for the language access protections under § 155.205(c)(2)(iii).

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[42] In particular, we note the separate requirement for entities covered under section 1557 of the Affordable Care Act that links to taglines from the home page of a covered entity's Web site must be posted as "in language" Web links, which are links written in each of the 15 non-English languages posted conspicuously on the home page that direct the individual to the full text of the tagline indicating how the individual may obtain language assistance services. For instance, a tagline directing an individual to a Web site with the full text of a tagline written in Haitian Creole should appear as "Kreyòl" rather than "Haitian Creole." (45 CFR 92.8(1)(iii); 81 FR 31396.)

[43] See 80 FR 10788.

c. Ability of States To Permit Agents and Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

Consistent with section 1312(e) of the Affordable Care Act, we established procedures under § 155.220 to support the States' ability to permit agents and brokers to assist individuals, employers or employees with enrollment in QHPs offered through an Exchange, subject to applicable Federal and State requirements. At § 155.220(c), we established parameters for enrollment of qualified individuals through an Exchange with the assistance of an agent or broker. At § 155.220(c)(1), we established that an agent or broker who assists with enrollment through the Exchange must ensure completion of an eligibility verification and enrollment application through the Exchange Web site as described § 155.405. In § 155.220(c)(3), we established standards that apply when using the direct enrollment pathway and a Web site of an agent or broker is used to complete the QHP selection. As described at § 155.220(d), an agent or broker that enrolls qualified individuals through an Exchange, or assists individuals in applying for Exchange financial assistance, must comply with the terms of a general agreement with the Exchange, as well as register with the Exchange and receive training in the range of QHP options and insurance affordability programs. In addition, all agents and brokers must execute the applicable privacy and security agreement required by § 155.260(b) to provide assistance with enrollment through the Exchange. We also established FFE standards of conduct under § 155.220(j) for agents and brokers that assist consumers in enrolling in coverage through the FFEs to protect consumers and ensure the proper administration of the FFEs. In this rulemaking, we propose to build on this foundation with the adoption of new procedures and additional consumer protection standards for agents and brokers that assist with enrollments through Exchanges. We also solicit additional comments to help further inform the development and implementation of the enhanced direct enrollment pathway.

i. Differential Display of Standardized Options on the Web Sites of Agents and Brokers

Under current rules, web-brokers and issuers that use the direct enrollment pathway to facilitate enrollment through an Exchange that offers standardized options are not required to give differential display to standardized options. In the 2017 Payment Notice, we noted that we would be conducting consumer testing to help us evaluate ways in which standardized options, when certified by an FFE, could be displayed on our consumer-facing plan comparison features in a manner that makes it easier to find and identify them, including distinguishing them from non-standardized plans. We noted that we anticipate differentially displaying the standardized options to allow consumers to compare plans based on differences in price and quality rather than cost-sharing structure, as well as providing information to explain the standardized options concept to consumers.

We added a new provision to § 155.205(b)(1) codifying the Exchange's authority to differentially display standardized options on our consumer-facing plan comparison and shopping tools. We did not require QHP issuers or web-brokers to adhere to differential display requirements of standardized options when using a non-Exchange Web site to facilitate enrollment in a QHP through an Exchange for the 2017 plan year, but we noted that we would consider whether to propose such a requirement in the future. Elsewhere in this document, we propose for the 2018 plan year and beyond, to allow SBE–FPs to choose to allow HHS-designed standardized options to receive differential display on *HealthCare.gov*, just as the plans would if offered through an FFE.

For the 2018 plan year and beyond, we propose to require web-brokers and issuers that use the direct enrollment pathway to differentially display standardized options when they facilitate enrollment through an FFE or an SBE–FP that has elected to implement differential display; however, we would not require the manner of differentiation to be identical to the one adopted for displaying standardized options on *HealthCare.gov*. We recognize that web-brokers and issuers may have system constraints that prevent them from mirroring the *HealthCare.gov* display approach, and so propose that if a web-broker or issuer that uses the direct enrollment pathway wants to deviate from the manner adopted by HHS for display on *HealthCare.gov*, such deviations would be permitted, subject to approval by HHS. In approving deviations, HHS would consider whether the same level of differentiation and clarity is being provided under the deviation requested by the web-broker or issuer as is provided on *HealthCare.gov*. Therefore, we propose to amend § 155.220(c)(3)(i) governing web-brokers by adding new paragraph (c)(3)(i)(H), and to amend § 156.265(b)(3) governing QHP issuers engaged in direct enrollment by adding new paragraph (b)(3)(iv) to require differential display of all standardized options in accordance with the requirements under § 155.205(b)(1) in a manner consistent with that adopted by HHS for display on the FFE Web site, unless HHS approves a deviation.

ii. Enhanced Direct Enrollment Process

In the 2017 Payment Notice (81 FR at 12258), we discussed a proposal to implement an enhanced direct enrollment process to facilitate enrollment through Exchanges that rely on the Federal platform for their eligibility and enrollment functions, namely FFEs or SBE–FPs. If we were to implement this process, it would be an additional option for a web-broker or QHP issuer to conduct direct enrollment activities; those entities could also continue to conduct direct enrollment through the current process, which requires a consumer to be redirected to *HealthCare.gov* in order to apply for coverage and receive an eligibility determination. In the 2017 Payment Notice, we discussed establishing an enhanced direct enrollment pathway, and stated that HHS would continue to analyze the necessary protections that need to be in place before moving forward with that new process. We now seek additional comments from the public as described below.

Under the direct enrollment process today, a consumer is redirected from the Web site of the direct enrollment partner (issuer or web-broker) to *HealthCare.gov* to complete the eligibility application and obtain an eligibility determination. Under the enhanced direct enrollment process that we are considering, a consumer might remain on the Web site of the direct enrollment partner (QHP issuer or web-broker) to submit information necessary for an eligibility determination without being redirected to *HealthCare.gov*. The enhanced direct enrollment partner would pass information collected for the eligibility application to the Exchange. The Exchange would then generate the eligibility determination and pass the eligibility results back to the enhanced direct enrollment partner. The consumer could see the results on the direct enrollment partner's Web site. Just as with the current direct enrollment process, the Exchanges would continue to make the eligibility determination under enhanced direct enrollment, and eligibility verification information the Exchanges receive from other government agencies would not be disclosed to the enhanced direct enrollment partner. We believe that an enhanced direct enrollment process would allow the consumer to have a more streamlined experience and would permit the Exchange to offer a diverse set of enrollment channels to reach consumers.

Although offering additional enrollment channels may make it easier for consumers to access coverage under qualified health plans, we must consider any additional risks this enrollment channel may pose to consumer privacy and the security of the consumer data that will be provided to enhanced direct enrollment partners. We solicit comment on these additional risks, as well as comment on any additional privacy and security safeguards and other consumer protections that should be implemented. We intend to conduct a privacy impact assessment as required by OMB Memorandum M–10–23. These comments will inform our identification and assessment of privacy and security risks presented by the enhanced direct enrollment pathway. This assessment will also help us to identify necessary safeguards that need to be in place to protect the personal data that consumers would entrust to enhanced direct enrollment partners.

iii. Additional Protections for the Current Direct Enrollment Process and FFE Standard of conduct for Agents and Brokers

We also propose in this rule a number of modifications to existing requirements and the establishment of new requirements for agents and brokers that use the current direct enrollment process to ensure adequate consumer protection if a web-broker is facilitating enrollment through an FFE or SBE–FP. We propose to make a number of the same changes to § 156.1230, which governs QHP issuers using direct enrollment, to ensure that consumers have similar protections when enrolling through a direct enrollment channel, whether they enroll using a web-broker, or a QHP issuer, and seek comment on whether any additional requirements should apply, or if any of these requirements should be modified, removed, or enhanced when applied to QHP issuers using the direct enrollment channel. First, we propose to add § 155.220(c)(3)(i)(I) to require web-brokers to display information provided by HHS pertaining to eligibility for the advance payments of the premium tax credit (APTC) and cost-sharing reductions in a prominent manner. This will increase the likelihood that consumers understand their potential eligibility for APTC and cost-sharing reductions and potential liability for excess APTC repayment, and can factor those determinations into their QHP selection and the amount of APTC they elect to take.

Second, under § 155.310(d)(2), an Exchange may only provide APTC if the Exchange receives certain attestations from the tax filer, and must permit an enrollee to accept less than the full amount of APTC for which the enrollee is eligible. Therefore, in order for an Exchange to provide APTC to a consumer who enrolls through the enhanced direct enrollment pathway, the direct enrollment partner must provide enrollees with an opportunity to input their desired amount of APTC and provide the required APTC-related attestations. HHS is aware that some web-brokers are not consistently permitting enrollees to select an amount for APTC under the existing direct enrollment pathway, and believes that permitting such would streamline the current direct enrollment pathway for consumers. Accordingly, we propose to add § 155.220(c)(3)(i)(J) to require web-brokers to allow consumers to select an APTC amount and make related attestations in accordance with the requirements of § 155.310(d)(2). We note that this would be consistent with 45 CFR 156.1230(a)(1)(v), under which QHP issuer direct enrollment partners are currently required to allow consumers to select an APTC amount and make related attestations.

Third, we propose to add § 155.220(c)(3)(i)(K) to require the agent or broker of record who assisted the consumer with enrollment through the Exchange (that is, the agent or broker whose National Producer Number is listed on the Exchange application) to support post-enrollment activities necessary for the consumer to effectuate his or her coverage or resolve issues related to his or her enrollment, including discrepancies related to eligibility. For example, we are aware of situations when consumers inadvertently failed to make their binder payments and lost their coverage without their knowledge. HHS would require the agent or broker to support the consumer to help ensure that consumers are educated about how to make the binder payment. Similarly, we would require the agent or broker to support the resolution of open data matching issues. We understand that many agents and brokers provide this type of assistance today to their clients after initial enrollment, helping with questions or problems that may arise regarding billing, claims or appeals. We believe that this proposal will help ensure that consumers who access an agent or broker's direct enrollment channel would have access to the skilled assistance and expertise of licensed agents and brokers beyond the initial QHP selection and enrollment process. We intend to provide further guidance on the extent of this required post-enrollment support, and solicit comment on types and extent of support that agents and brokers should be required to provide. We also solicit comments on what additional safeguards, if any, should be put in place to protect consumers and their data.

Fourth, we propose to add § 155.220(c)(3)(i)(L) to require web-brokers to demonstrate operational readiness, including compliance with applicable privacy and security requirements, prior to accessing either the current or enhanced direct enrollment pathway. This is intended to build upon the onboarding and testing process that web-brokers undergo under existing procedures for the current direct enrollment process. This process would require the web-broker to demonstrate that it has implemented required privacy and security measures and that it satisfies the technical specifications, testing requirements, and onboarding procedures applicable to the direct enrollment process that the web broker is using prior to accessing the Exchange. Consistent with § 155.220(c)(5), we intend to conduct ongoing monitoring and audits to verify that compliance throughout the term of the web-broker's registration with the Exchange.

Fifth, we propose adding § 155.220(c)(3)(i)(M), to allow HHS to immediately suspend the agent or broker's ability to transact information with the Exchange as part of the direct enrollment pathway if HHS discovers circumstances that pose unacceptable risk to Exchange operations or its information technology systems. The suspension would last until HHS is satisfied that the risk has been removed or sufficiently mitigated. For example, a web-broker's access to the direct enrollment pathway may be suspended if it is determined that the web-broker is using an enrollment process other than the HHS-approved processes, presenting a risk of inaccurate eligibility determinations or presenting unacceptable security or privacy risks to consumer data. We note that this direct enrollment requirement is similar to the one at § 155.220(c), which applies to agents or brokers making their Web site available to another agent or broker. We seek comment on whether these or other similar requirements should be combined. In addition, we propose to add language to § 155.220(c)(3)(i)(E) to require an agent or broker to cooperate with any audit under this section. This would include responding to requests for information in a timely fashion, as well as providing access upon request to documents or other materials necessary to confirm compliance with applicable requirements.

Sixth, consistent with § 155.220(c)(4), web-brokers are permitted to provide access, through a contract or other arrangement, to their direct enrollment pathway to another agent or broker to help an applicant complete the QHP selection process, and must comply with certain obligations when doing so. We understand that a number of web-brokers provide access to their direct enrollment pathway to other agents and brokers who host their own third-party Web sites. To better protect consumers accessing these downstream third-party Web sites that connect to the web-broker's direct enrollment pathway, we are proposing to add language to § 155.220(c)(4)(i)(E) to require web-brokers that provide this access to be responsible for ensuring those Web sites are compliant with this section.

HHS is also considering different methods for completing the monitoring and audits authorized by § 155.220(c)(5). For example, HHS, its designee, or an approved third party could perform the onboarding testing or audit. Where approved third parties perform onboarding reviews and audits, we anticipate that they would be approved by HHS and would need the capability to audit web-brokers' ability to securely collect, maintain, and transmit eligibility application information in a manner determined by HHS and to otherwise review compliance with HHS rules. For third parties to be approved to conduct these activities, we expect that the auditor would need to submit an application to HHS demonstrating prior experience in verifying these sorts of capabilities, and, if approved, enter into an agreement with HHS governing the auditor's compliance with HHS audit and verification standards, interface with HHS systems, and data use. The auditor would be required to collect, store, and share data with HHS on these verifications, and protect that data in accordance with HHS standards. The auditor would be subject to monitoring and periodic certification by HHS, and would be compensated by the agents or brokers who engaged the auditor. If HHS elects to allow third parties to perform such verifications, we would establish a process for evaluating and approving third party vendors in a manner similar to the one established in § 155.222. We solicit comment on our proposal to allow third parties to perform monitoring and audits authorized by § 155.220(c). We also seek comment on whether we should establish a process for recognizing third parties to perform such monitoring, what protections are needed, and the factors HHS should consider in evaluating and approving organizations for this type of role.

Finally, we propose to amend § 155.220(j)(2)(i) to provide that an agent or broker that assists with or facilitates enrollment of qualified individuals in a manner that constitutes enrollment through an FFE or SBE–FP, or assists individuals in applying for APTC and cost-sharing reductions for QHPs sold through an FFE or SBE–FP, must refrain from having a Web site that HHS determines could mislead consumers into believing they are visiting *HealthCare.gov*. For example, our experience shows that Web sites that utilize combinations of colors, text sizes and fonts or layout similar to those used on *HealthCare.gov* have caused confusion among consumers. Web sites whose URL address or marketing name could suggest the Web site is owned or endorsed by *HealthCare.gov* would also be inappropriate. We believe that it is important to avoid consumer confusion around which Web sites are operated by the FFE or SBE–FP, and which ones are operated by issuers, or agents or brokers. We would be interested in feedback on criteria for determining whether a Web site is misleading to consumers.

We seek comment on all aspects of this proposal and specifically seek comment on whether direct enrollment with a QHP issuer should be permitted for enrollments through all SBE–FPs, or at the option of SBE–FPs.

d. General Standards for Exchange Notices (§ 155.230)

Section 155.230 outlines standards for notices required to be sent by the Exchange to individuals or employers. We propose amending paragraph § 155.230(d)(2) to specify that electronic notices would be the default method for sending required SHOP Exchange notices, unless otherwise required by Federal or State law. The proposed amendment would make mailed paper notices optional, at the election of the employer or employee, as applicable, unless other Federal or State law would not permit this.[44] We propose this change because we have received feedback from SHOP consumers and issuers that electronic notices are the preferred method of communication. In addition, electronic notices provide a more cost effective way for SHOPs to distribute required notices. However, we are aware that some people (and employers) may still prefer mailed paper notices, and therefore propose that paper notices distributed through standard mail would continue to be available for those that select paper notices as the preferred method of communication. Employers and employees participating in FF–SHOPs or in SBE–FPs utilizing the Federal platform for SHOP functions will continue to be able to select their preferred communication method when completing the eligibility applications online at *HealthCare.gov*. We note that to the extent that a SHOP is required to provide notices in a particular format to meet its obligation to perform effective communication with an individual with a disability under the Americans with Disabilities Act of 1990 (42 U.S.C. Ch. 126), section 504 of the Rehabilitation Act, or section 1557 of the Affordable Care Act, a SHOP should comply with those requirements.

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[44] See Federally-facilitated Marketplace (FFM) and Federally-facilitated Small Business Health Options Program (FF–SHOP) Enrollment Manual available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/ENR_FFMSHOP_Manual_080916.pdf*, for a list of the FF–SHOP Exchange notices.

We note that this amendment would not change the requirement that a SHOP comply with the requirements for electronic notices in 42 CFR 435.918(b)(2) through (5) for the employer or employee. We seek comment on this proposal.

We also propose to add a new paragraph § 155.230(d)(3) to give individual market Exchanges and SHOPs flexibility to send notices through standard mail, instead of electronically, if an individual market Exchange or SHOP is unable to send select notices electronically due to technical limitations, even if an election has been made to receive such notices electronically. Our regulation currently requires that, should an individual's, employee's, or employer's notice preference be electronic notices, an individual market Exchange must send required notices according to this preference, and our proposed amendment to paragraph (d)(2) would require that a SHOP provide electronic notices unless paper notices are selected as the preferred communication method. However, Exchanges or SHOPs may have technological limitations that prevent them from sending certain notices electronically. In these situations, we would like to provide flexibility for an individual market Exchange or SHOP to instead notify the individual, employee, or employer through standard mail. We encourage individual market Exchanges or SHOPs who might need to exercise this option to explain to individuals, employees, or employers that some required notices may be sent through standard mail, and encourage additional outreach be conducted, as needed, so the individual, employee, or employer understands the content of the standard mail notice itself. We seek comment on this proposal.

e. Payment of Premiums (§ 155.240)

When an enrollee stops receiving the benefit of advance payments of the premium tax credit, for example as a result of a data matching inconsistency period expiring, the enrollee will be responsible for a greater premium amount. For individuals who have agreed to pay premiums via electronic funds transfer (EFT), this could mean the withdrawal of a larger than expected amount from the enrollee's bank account, and could result in financial hardship. We recognize that issuers have different procedures in place to provide notice to enrollees affected by a larger-than-expected EFT withdrawal and to avoid potential consumer hardship. We are considering future rulemaking that would require safeguards for consumers, such as reversal or termination of EFTs, with or without simultaneous paper-billing, when EFT amounts are of a larger-than-expected amount. We seek comment regarding the scope of any potential problem related to larger-than-expected EFT withdrawals, issuers' experience with these withdrawals, industry best practices, State regulations in this area, and whether Federal rulemaking is needed.

3. Exchange Functions in the Individual Market: Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

a. Eligibility Redetermination During a Benefit Year (§ 155.330)

Paragraph (d)(1)(ii) of § 155.330 requires the Exchange to periodically examine available data sources for eligibility determinations for certain government health programs, including Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), for Exchange enrollees on whose behalf APTC or the cost-sharing reduction portion of advance payments are being paid. We are proposing to amend paragraph (d)(1)(ii) to require the Exchange to periodically examine data sources for information on either eligibility determinations for or enrollment in the specified government programs.

The proposed change would provide Exchanges with flexibility to use information about enrollment in the specified government health programs, rather than information about eligibility determinations. Having this flexibility may be particularly valuable if data on eligibility determinations (as distinct from enrollment) are not available. When deciding whether to examine data sources for eligibility determinations or enrollment information, Exchanges should consider which data source best meets the criteria of timeliness, accuracy, and availability.

We propose to add a new paragraph § 155.330(e)(2)(iii) related to periodic examination of data sources. Currently, paragraph (e)(2)(i) describes the procedures for redetermination and notification of eligibility when, through a data matching process under § 155.330(d), an Exchange identifies updated information regarding death or any factor of eligibility not regarding income, family size, or family composition. Our regulations have not previously addressed how an Exchange should use updated information regarding compliance with the income tax filing and reconciliation requirement under § 155.305(f)(4). Due to certain operational and legal impediments explained below, we believe that the procedures in paragraph (e)(2)(i) may not be appropriate in these cases. Proposed new paragraph (e)(2)(iii) would require an Exchange to choose among three alternatives for when the Exchange identifies updated information regarding compliance with the income tax filing and reconciliation requirement under § 155.305(f)(4): (A) Follow the procedures specified in paragraph (e)(2)(i) of this section; (B) follow alternative procedures specified by the Secretary in guidance; or (C) follow an alternative process proposed by the Exchange and approved by the Secretary based on a showing that the process meets the approval criteria outlined below.

An Exchange enrollee's continued eligibility for APTC may be jeopardized when the person responsible for reconciling the tax credit on a tax return fails to do so as required in § 155.305(f)(4). However, Exchange operational concerns, the need for close cooperation with the IRS, timelines for tax filing (including requesting an extension of the tax filing deadline), timelines for updating the IRS database that provides information about income tax return filing and reconciliation, and restrictions on the disclosure of Federal tax information affect an Exchange's processes for making redeterminations and communicating with enrollees regarding redeterminations.

In light of these complexities, specific procedures for handling these redeterminations may be warranted that balance Exchange operational flexibility, the need for program integrity protections and procedural protections for enrollees and tax filers. Accordingly, under proposed paragraph (e)(2)(iii), Exchanges must follow the procedures specified in § 155.330(e)(2)(i) (provided the Exchange is able to maintain adequate safeguards for Federal tax information consistent with section 6103 of the Code with respect to the confidentiality, disclosure, maintenance, or use of such information), procedures described in guidance published by the Secretary, or alternative procedures approved by the

Secretary. The guidance established by the Secretary could, for example, provide that an Exchange would follow specified procedures for providing notice and, if there is a dispute about the IRS tax filing data regarding the tax filer (or his or her spouse, if applicable), provide an opportunity for the enrollee to contest.

An Exchange would also be permitted to choose alternative procedures for periodic data matching to verify whether a tax filer has complied with the filing and reconciliation requirement, subject to approval by the Secretary. Approval would require a showing by the Exchange that the alternative procedures would facilitate continued enrollment in coverage with financial assistance for which the enrollee remains eligible, provide appropriate information about the process to the enrollee (including regarding any action by the enrollee necessary to obtain the most accurate redetermination of eligibility), and provide adequate program integrity protections and safeguards for Federal tax information under section 6103 of the Code with respect to the confidentiality, disclosure, maintenance, or use of such information.

Additionally, in paragraph (g), we propose to allow alternate methods of recalculating APTC during the benefit year. Currently, paragraph (g) provides that when an Exchange makes an eligibility redetermination in accordance with § 155.330 that results in a change in the amount of APTC, the Exchange must recalculate the amount of APTC to account for any payments already made on behalf of the tax filer for the benefit year. The goal of the recalculation is to provide the total advance payments for the benefit year that correspond to the tax filer's total projected and allowed premium tax credit for the benefit year.

We propose for coverage years through 2023 to permit the Exchange to recalculate APTC in accordance with an eligibility redetermination under § 155.330 using an alternate method approved by the Secretary. Approval would require a showing by the Exchange that the alternative procedure provides adequate program integrity protections, minimizes administrative burden on the Exchange, and limits negative impacts on consumers, where possible. We make this change based on Exchange feedback and believe the proposed change will account for the differences in Exchange systems and mitigate complexities. We believe this change balances the need for Exchange flexibility in the near term with the goal of providing accurate determinations for APTC and protecting tax filers from the potential for an excess APTC repayment, where possible. We seek comment on this proposal and on the period of time for which it should be available.

We seek comment on these proposals.

4. Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

a. Enrollment of Qualified Individuals into QHPs (§ 155.400)

We propose to amend § 155.400 to add additional flexibility to the binder payment rules. Specifically, we propose to add § 155.400(e)(2) to give Exchanges the discretion to allow issuers experiencing billing or enrollment problems due to high volume or technical errors to implement a reasonable extension of the binder payment deadlines the issuer has set under § 155.400(e)(1). We propose that the FFEs and SBE–FPs will, and State Exchanges may, allow these reasonable extensions, which in the case of most high volume situations or technical errors we would not expect to be more than 45 calendar days' duration. Based on our experience from multiple open enrollment periods, billing or enrollment problems, particularly in cases where an issuer experienced technical errors or a processing backlog caused by a large volume of enrollments, can affect enrollees' ability to submit timely binder payments. We believe providing issuers with the option to allow reasonable binder payment deadline extensions, which must be implemented in a uniform and nondiscriminatory manner, would prevent enrollees from having their coverage cancelled due to non-payment when those enrollees did not have adequate time to make their binder payments and appropriately balances issuer flexibility and consumer protectiveness.

We also propose to specify that all binder payment rules, including the proposed amendment, in § 155.400(e) apply to SBE–FPs in addition to FFEs. We believe that all entities on the Federal platform should utilize the same binder payment rules in order to simplify operational implementation of enrollment processing and confirmation using the Federal platform, and consider these rules to fall within the regulations pertaining to issuer eligibility and enrollment functions that a QHP issuer must comply with in order to participate in an SBE–FP, under § 156.350. We seek comment on this proposal.

Additionally, in the preamble to § 156.270 in the 2017 Payment Notice, we stated as part of our interpretation of § 156.270(d) that a binder payment is not necessary when an enrollee enrolls, either actively or passively, in a plan within the same insurance product. We understand that this may be different than issuer practice prior to the Affordable Care Act and that issuers may have operational challenges in distinguishing between enrollment in the same product versus a different product. To minimize operational concerns, we seek comment on whether we should amend the binder payment requirement in § 155.400(e) to not require a binder payment when a current enrollee enrolls, either actively or passively, in any plan with the same issuer, and on the appropriate timeframe for making such a change.

b. Special Enrollment Periods (§ 155.420)

Special enrollment periods, a longstanding feature of employer-sponsored coverage, exist to ensure that people who lose health insurance during the year, or who experience other qualifying events, have the opportunity to enroll in coverage. We are committed to making sure that special enrollment periods are available to those who are eligible for them and equally committed to avoiding any misuse or abuse of special enrollment periods.

In 2016, we added warnings on *HealthCare.gov* about inappropriate use of special enrollment periods, eliminated special enrollment periods that are no longer needed as the Exchanges mature, and tightened eligibility rules. In addition, we introduced a special enrollment confirmation process under which consumers enrolling through the most common special enrollment periods are directed to provide documentation to confirm their eligibility for the special enrollment period.

We have heard competing concerns about how these actions are affecting the Exchange risk pools. Some have stated that additional changes are needed to prevent individuals from misusing special enrollment periods to sign up for coverage only after they become sick.[45] Others have stated that any differential costs for the special enrollment period population reflect the very low take-up rates for special enrollment periods among eligible individuals. They claim that verification processes worsen the problem by creating new barriers to enrollment, with healthier, less motivated individuals, the most likely to be deterred.

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[45] We have heard similar concerns about potential gaming and adverse selection that could result from the grace period for payment of premiums for qualified individuals receiving advance payments of the premium tax credit. While we seek additional information on this concern as well, we expect that changes to grace period policy would require legislation.

We seek comment on these issues, especially data that could help distinguish misuse of special enrollment periods from low take-up of special enrollment periods among healthier eligible individuals, evidence on the impact of eligibility verification approaches, including pre-enrollment verification, on health insurance enrollment, continuity of coverage, and risk pools (whether in the Exchange or other contexts), and input on what special enrollment period-related policy or outreach changes, including in the final rule, could help strengthen risk pools.

In this rule, we also seek to ensure transparency, stability, and appropriate utilization of special enrollment periods by codifying certain special enrollment periods that were made available through prior guidance. Therefore, in order to provide clarity and certainty to all stakeholders, we propose to codify:

- Paragraph (d)(8)(ii) for the special enrollment period for dependents of Indians who are enrolled or are enrolling in a QHP through an Exchange at the same time as an Indian;
- Paragraph (d)(10) for the special enrollment period for victims of domestic abuse or spousal abandonment and their dependents who seek to apply for coverage apart from the perpetrator of the abuse or abandonment;
- Paragraph (d)(11) for the special enrollment period for consumers and their dependents who apply for coverage and are later determined ineligible for Medicaid or CHIP;
- Paragraph (d)(12) for the special enrollment period that may be triggered by material plan or benefit display errors on the Exchange Web site, including errors related to service areas, covered services, and premiums; and
- Paragraph (d)(13) for the special enrollment period that may be triggered when a consumer resolves a data matching issue following the expiration of an inconsistency period.

We propose to codify the special enrollment period for dependents of Indians who are enrolling at the same time as the Indian, as defined by section 4 of the Indian Health Care Improvement Act, in paragraph (d)(8)(ii) so that Indians and non-Indian members of the household may maintain the same coverage and so that this special enrollment period is consistently applied across Exchanges. This special enrollment period has enabled mixed status Indian families to enroll in or change coverage together through the Exchange. We propose to codify the special enrollment period for victims of domestic abuse or spousal abandonment in paragraph (d)(10) so that, as specified in July 2015 guidance,[46] victims of domestic abuse or spousal abandonment, along with their dependents, can enroll in coverage separate from their abuser or abandoner. This special enrollment period has provided a needed pathway to new coverage for consumers in these situations. We propose to codify the special enrollment period for consumers who apply for coverage during the Exchange annual open enrollment period or due to a qualifying event and are determined ineligible for Medicaid or CHIP in paragraph (d)(11), so that consumers who applied for coverage when they were eligible to do so can ultimately enroll in coverage through the Exchange. This special enrollment period has ensured that consumers who were incorrectly assessed potentially eligible for Medicaid or CHIP have a pathway to coverage. We propose to codify the special enrollment period for material plan or benefit display errors in paragraph (d)(12), so that consumers who enrolled in a plan based on incorrect plan or benefit information can select a new plan that better suits their needs. We propose to codify the special enrollment period for data matching issues that are cleared after the deadline for resolving has passed in paragraph (d)(13), so that consumers who submit required documents to prove that they are qualified individuals may enroll in coverage through the Exchange. This special enrollment period has enabled consumers who are not able to submit required documents prior to the deadline associated with their data matching issue to enroll in coverage upon submitting sufficient documents. We seek comments on these proposals to codify existing special enrollment periods.

We also propose to make a variety of technical corrections to correct punctuation in paragraphs (d)(1)(i) and (iii), and to update the cross-references in paragraph (b)(2)(iii) (regarding coverage effective dates) to reflect the applicable newly codified special enrollment periods. All of these changes reflect existing FFE practice in implementing special enrollment periods authorized by the Affordable Care Act and existing regulations, and do not create new special enrollment periods for consumers.

We note that certain special enrollment periods in § 155.420 are incorporated into the individual market guaranteed availability regulations at § 147.104(b) and apply to all issuers offering non-grandfathered individual market coverage, whether through or outside of an Exchange. Additionally, certain special enrollment periods in § 155.420 also apply in the SHOPs and are incorporated into the SHOP regulations at §§ 155.725(j) and 156.285(b). Except for the proposed additions of paragraphs (d)(8)(ii) and (d)(13), which are applicable only with respect to coverage offered through an Exchange, the proposed changes to special enrollment periods in this notice of proposed rulemaking would apply throughout the individual market, and we therefore propose conforming amendments to § 147.104(b). We seek comment on this approach to aligning the proposed amendments with the individual-market-wide and SHOP special enrollment periods.

c. Termination of Exchange Enrollment or Coverage (§ 155.430)

We propose to amend § 155.430(b)(2)(iii) to specify that when an issuer seeks to rescind coverage, in accordance with § 147.128, in a QHP purchased through an Exchange, the issuer must first demonstrate, to the reasonable satisfaction of the Exchange, that the rescission is appropriate, if so required by the Exchange. In FFEs and SBE–FPs, HHS anticipates generally requiring such a demonstration. Section 2712 of the PHS Act and § 147.128 prohibit an issuer from rescinding coverage unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. We do not seek to restrict issuers' ability to rescind coverage when an individual or a party seeking coverage on behalf of an individual fraudulently enrolls the individual in coverage. However, because the Exchanges generally must be involved in all enrollment processes, including the process of rescinding coverage for plans purchased through the Exchange, it is necessary for the issuer to provide information to the Exchange in order to implement the rescission. Additionally, it is important for consumer protection and the orderly functioning of Exchanges that individuals whose eligibility has been verified and enrollments processed according to Exchange rules can be sure that their coverage will not be rescinded by issuers without a showing that the enrollment was fraudulent, or due to an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage, meeting the requirements for rescission under § 147.128. The FFEs or SBE–FPs would not hinder an issuer seeking to rescind on grounds demonstrating fraud or intentional misrepresentation of material fact, such as the enrollment of a non-existent or deceased person. We seek comment on this proposal.

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[46] Updated Guidance on Victims of Domestic Abuse and Spousal Abandonment (Jul. 27, 2015). Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Updated-Guidance-on-Victims-of-Domestic-Abuse-and-Spousal-Abandonment_7.pdf.*

5. Appeals of Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

a. General Eligibility Appeals Requirements (§ 155.505)

In § 155.505, we propose to add paragraph (h) permitting the Exchange appeals entity to utilize paper-based appeals processes for the acceptance of appeal requests, the provision of appeals notices, and the secure transmission of appeals-related information between entities, when the Exchange appeals entity is unable to establish and perform otherwise required related electronic functions, as further described below. In the first Program Integrity Rule, 78 FR 54069 (Aug. 30, 2013), we provided flexibility for Exchanges to implement a paper-based appeals process for the first year of operations (October 1, 2013 through December 31, 2014). Our goal was to allow Exchanges to operate efficient, effective paper-based appeals processes, while providing time to modernize their appeals programs. We believed this approach balanced the interests of both appellants and Exchanges.

We extended this flexibility through December 31, 2016 in guidance published on October 23, 2014[47] and March 22, 2016.[48] In these documents, we acknowledged that Exchanges face many challenges and competing priorities regarding system development. Currently, some Exchange appeals entities are continuing to work towards full compliance with the regulatory requirements related to electronic appeals processes.

Accordingly, we are proposing to add § 155.505(h) so the Exchange appeals entity may establish secure and expedient paper-based appeals processes that ensure appropriate procedural protections for appellants when it is unable to fulfill the electronic requirements related to individual market eligibility appeals, employer appeals, and SHOP employer and employee appeals as described in part 155, subparts C, D, F, and H. These electronic requirements include: Accepting appeal requests submitted by telephone or internet (§ 155.520(a)(1)(i) and (iv)), sending electronic notices (§ 155.230(d)), and establishing secure electronic interfaces to transfer eligibility and appeal records between appeals entities and Exchanges or Medicaid or CHIP agencies (§ 155.345(i)(1); § 155.510(b)(1)(ii) and (b)(2); § 155.520(d)(1)(ii) and (iii) and (d)(3) and (4); § 155.545(b)(3); § 155.555(e)(1); and § 155.740(h)(1)). We are also proposing corresponding amendments to § 155.555(b) (regarding employer appeals) and § 155.740(b)(2) (regarding SHOP appeals) to include cross-references to proposed § 155.505(h).

This proposal addresses the ongoing challenge of implementing complex electronic appeals processes, while adequately protecting appellants' procedural rights. We expect that appeals entities will continue to work towards modernizing and automating their appeals processes, and that they will implement electronic appeals processes as they are able, to the extent such processes may enhance appellants' experience or the overall efficiency of eligibility appeals.

We seek comment on this proposal.

b. Employer Appeals Process (§ 155.555)

Section 155.555(b) sets forth the requirements for employer appeals processes established either by an Exchange or HHS. As described above, we propose to amend § 155.555(b) to include cross-references to proposed § 155.505(h), which would permit an employer appeals process to utilize paper-based appeals processes for the acceptance of appeal requests, the provision of appeals notices, and the secure transmission of appeals-related information between entities, when the Exchange appeals entity is unable to establish and perform otherwise required related electronic functions.

6. Required Contribution Percentage (§ 155.605(e)(3))

Under section 5000A of the Code, an individual must have minimum essential coverage for each month, qualify for an exemption, or make a shared responsibility payment with his or her Federal income tax return. Under section 5000A(e)(1) of the Code, an individual is exempt if the amount that he or she would be required to pay for minimum essential coverage (the required contribution) exceeds a particular percentage (the required contribution percentage) of his or her actual household income for a taxable year. In addition, under § 155.605(d)(2), an individual is exempt if his or her required contribution exceeds the required contribution percentage of his or her projected household income for a year. Finally, under § 155.605(d)(2)(iv), certain employed individuals are exempt if, on an individual basis, the cost of self-only coverage is less than the required contribution percentage, but the aggregate cost of individual coverage through employers exceeds the required contribution percentage, and no family coverage is available through an employer at a cost less than the required contribution percentage.

Section 5000A established the 2014 required contribution percentage at 8 percent. For plan years after 2014, section 5000A(e)(1)(D) of the Code and 26 CFR 1.5000A–3(e)(2)(ii) provide that the required contribution percentage is the percentage determined by the Secretary of HHS that reflects the excess of the rate of premium growth between the preceding calendar year and 2013, over the rate of income growth for that period.

We established a methodology for determining the excess of the rate of premium growth over the rate of income growth for plan years after 2014 in the 2015 Market Standards Rule (79 FR 30302), and we said future adjustments would be published annually in the HHS notice of benefit and payment parameters.

Under the HHS methodology, the rate of premium growth over the rate of income growth for a particular calendar year is the quotient of (x) 1 plus the rate of premium growth between the preceding calendar year and 2013, carried out to ten significant digits, divided by (y) 1 plus the rate of income growth between the preceding calendar year and 2013, carried out to ten significant digits.[49]

As the measure of premium growth for a calendar year, we established in the 2015 Market Standards Rule that we would use the premium adjustment percentage. The premium adjustment percentage is based on projections of average per enrollee employer-sponsored insurance premiums from the National Health Expenditure Accounts (NHEA), which are calculated by the CMS Office of the Actuary.[50] (Below, in § 156.130, we propose the 2018 premium adjustment percentage of 16.17303196 (or an increase of about 16.2 percent) over the period from 2013 to 2017. This reflects an increase of about 2.6 percent over the 2017 premium adjustment percentage (1.1617303196/1.1325256291).)

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[47] Subregulatory Guidance Memorandum (Oct. 23, 2014), *available at https://www.cms.gov/CCIIO/Resources/Regulations-andGuidance/Downloads/Paper-based-Appeals-Process-Guidance.pdf.*

[48] Subregulatory Guidance Memorandum (Mar. 22, 2016), *available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Extension-for-paper-based-appeals-3-22-2016.pdf*).

[49] We also defined the required contribution percentage at § 155.600(a) to mean the product of 8 percent and the rate of premium growth over the rate of income growth for the calendar year, rounded to the nearest one-hundredth of one percent.

As the measure of income growth for a calendar year, we established in the 2017 Payment Notice that we would use per capita personal income (PI). Under the approach finalized in the 2017 Payment Notice, and using the NHEA data, the rate of income growth for 2018 is the percentage (if any) by which the most recent projection of per capita PI for the preceding calendar year ($51,388 for 2017) exceeds per capita PI for 2013 ($44,528), carried out to ten significant digits. The ratio of per capita PI for 2017 over the per capita PI for 2013 is estimated to be 1.1540603665 (that is, per capita income growth of about 15.4 percent). This reflects an increase of about 4.0 percent relative to the increase for 2013 to 2016 (1.1540603665/1.1101836394).

Thus, using the 2018 premium adjustment percentage proposed in this rule, the excess of the rate of premium growth over the rate of income growth for 2013 to 2017 is 1.1617303196/1.1540603665, or 1.0066460588. This results in a proposed required contribution percentage for 2018 of 8.00*1.0066460588, or 8.05 percent, when rounded to the nearest one-hundredth of one percent, a decrease of 0.11 percentage points from 2017 (8.05317 − 8.16100). The excess of the rate of premium growth over the rate of income growth also is used for determining the applicable percentage in section 36B(b)(3)(A) and the required contribution percentage in section 36B(c)(2)(C).

7. Enrollment Periods Under SHOP (§ 155.725)

Section 155.725(g) describes the process for newly qualified employees to enroll in coverage through a SHOP and the coverage effective date for newly qualified employees. We propose to amend paragraphs (g)(1) and (2) and add new paragraph (g)(3).

Currently, § 155.725(g)(1) requires both that: (1) The enrollment period for an employee who becomes a qualified employee outside of the initial or annual open enrollment period starts on the first day of becoming a newly qualified employee; and (2) a newly qualified employee must have at least 30 days from the beginning of his or her enrollment period to make a plan selection. The latter requirement is intended to guarantee that the employee has sufficient time to make an informed decision about his or her health coverage needs. We do not propose changes to this latter requirement, but we propose to change the day the enrollment period begins.

Before a newly qualified employee may make a plan selection through a SHOP, his or her employer must notify the SHOP about the newly qualified employee. Qualified employers in an FF–SHOP or SBE–FP using the Federal platform for SHOP eligibility or enrollment functions generally report newly qualified employees by adding the employee to the employee roster or by calling the FF–SHOP call center. If, however, a qualified employer waits to take either action, a newly qualified employee might not be able to begin the enrollment process until after the date upon which the employee became eligible, and might not have a full 30 days to make a coverage decision, as contemplated by the current regulations. We are concerned that there might be a similar delay in State-based SHOPs.

To ensure that newly qualified employees have the full 30 days to enroll, we propose, at § 155.725(g)(1), that SHOPs would be required to provide an employee who becomes a qualified employee outside of the initial or annual open enrollment period with a 30-day enrollment period that begins on the date the qualified employer notifies the SHOP about the newly qualified employee. We also propose that qualified employers would be required to notify the SHOP about a newly qualified employee on or before the 30th day after the day that the employee becomes eligible for coverage, and are also proposing a conforming amendment to the requirements for qualified employers at § 157.205(f)(1). Together with the other proposed amendments to paragraph (g) discussed below, this proposal would ensure that the proposed policy of starting the 30-day enrollment period on the date of the qualified employer's notice to the SHOP would not delay the effective date of coverage beyond the limits on waiting periods imposed under § 147.116, and would also ensure that newly qualified employees are provided with a full 30 days to make their health coverage decisions after their employer has notified the SHOP about them.

We also propose to remove the requirement in current § 155.725(g)(1) that enrollment periods for newly qualified employees must end no sooner than 15 days prior to the date that any applicable employee waiting period longer than 45 days would end if the employee made a plan selection on the first day of becoming eligible. We are proposing to remove this requirement because the proposed amendments at paragraphs (g)(2) and (3) discussed below are expected to minimize the risk of employers exceeding waiting period limitations, as defined at § 147.116, and because we believe that removing this requirement will in some circumstances give newly qualified employees a longer period of time to make coverage decisions. For example, suppose that a new employee who is not a variable hour employee is hired and offered coverage by the qualified employer on April 25 and that the qualified employer imposes a 60-day waiting period that begins on the date of hire (and under § 147.116 and the proposed amendments to paragraph (g)(3) discussed below ends June 23). The qualified employer notifies the SHOP on May 25 about the newly qualified employee, and the enrollment period begins on that date and will end on June 23. The newly qualified employee makes a plan selection on May 26. If we maintained the requirements that coverage effective dates for newly qualified employees must generally be determined in accordance with § 155.725(h) (see discussion below of proposed amendments to this requirement) and that enrollment periods for newly qualified employees must begin on the date that the employee becomes eligible, and end no sooner than 15 days prior to the date that any applicable employee waiting period longer than 45 days would end if the employee made a plan selection on the first day of becoming eligible, the newly qualified employee's enrollment period would have ended on June 9 and the employee would have a coverage effective date of July 1. However, under the proposed amendments we are making to this section, the newly qualified employee would be provided a full 30-day enrollment period with the same coverage effective date of July 1.

Current paragraph (g)(2) provides that a newly qualified employee's coverage effective date must always be the first day of a month, and must generally be determined in accordance with paragraph (h), unless the employee is subject to a waiting period consistent with § 147.116, in which case the effective date may be on the first day of a later month, but in no case may the effective date fail to comply with § 147.116. Thus, in an FF–SHOP, under the current rule, coverage for a newly qualified employee generally takes effect the first day of the following month for a plan selection made on or before the 15th day of a month, and takes effect the first day of the second following month for a plan selection made after the 15th day of a month, unless coverage must take effect on a later date due to the application of a waiting period consistent with § 147.116. We propose to modify paragraph (g)(2) to specify that the coverage effective date for a newly qualified employee would be the first day of the month following the plan selection, (rather than being determined in accordance with paragraph (h)), unless the employee is subject to a waiting period consistent with § 147.116 and proposed paragraph (g)(3), in which case the effective date would be on the first day of the month following the end of the waiting period, but in no case may the effective date fail to comply with § 147.116. The proposed amendments to paragraph (g)(2) also specify that: (1) If a newly qualified employee's waiting period ends on the first day of a month and the employee has already made a plan selection by that date, coverage would also be effective on that date; and (2) if a newly qualified employee makes a plan selection on the first day of a month and any applicable waiting period has ended by that date, coverage would be effective on that date. These amendments would minimize the risk of an employer exceeding the limitations on waiting period length at § 147.116 due to SHOP enrollment timelines and processes.

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[50] For any given year the premium adjustment percentage is the percentage (if any) by which the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for the current year exceeds the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for 2013.

Additionally, in order to ensure that SHOP operations consistent with these proposed amendments would not cause a qualified employer to exceed the limits on waiting periods under § 147.116, we propose to amend § 155.725(g)(2) to require that if a qualified employer with variable hour employees makes regularly having a specified number of hours of service per period (or working full-time) a condition of employee eligibility for coverage offered through a SHOP, any measurement period that the qualified employer uses to determine eligibility under § 147.116(c)(3)(i) must not exceed 10 months with respect to coverage offered through the SHOP (rather than the 12-month measurement period otherwise allowed under § 147.116(c)(3)(i)). This aspect of the proposal is intended to ensure that coverage takes effect within the limitations on waiting period length at § 147.116(c)(3)(i) for variable hour employees, under which coverage must take effect no later than 13 months from the employee's start date, plus, if the employee's start date is not the first day of a calendar month, the time remaining until the first day of the next calendar month. Specifically, for qualified employers that condition eligibility for coverage on an employee regularly having a specified number of hours of service per period (or working full-time), if it cannot be determined that a newly-hired employee is reasonably expected to regularly work that number of hours per period (or work full-time), the qualified employer may take a reasonable period of time, not to exceed 10 months and beginning on any date between the employee's start date and the first day of the first calendar month following the employee's start date, to determine whether the employee meets the eligibility condition.

We seek comment on whether any of the proposed timeframes might result in a situation in which an employer or issuer falls out of compliance with § 147.116.

Consistent with § 147.116, as long as the employee subject to a waiting period may make a plan selection that results in coverage becoming effective within the timeframes required under § 147.116, coverage that begins later as a result of the employee's delay in making a plan selection would not constitute a failure to comply with the waiting period limitations under § 147.116. As a result of our proposal at paragraph (g)(2) of this section, when a newly qualified employee subject to a waiting period makes a plan selection, coverage would begin the first day of the first month that follows the expiration of the waiting period, as long as that date is consistent with the requirements in § 147.116. However, if the first day of the first month following the expiration of the waiting period for this employee would be outside the limits under § 147.116, the SHOP would be required under paragraph (g)(2) to ensure that coverage takes effect within the required timeframe. To avoid this scenario and the operational complications it would cause for SHOPs, we are also proposing to specify in a new paragraph (g)(3) that waiting periods in a SHOP may not exceed 60 days in length. If an individual subject to a waiting period could have had an effective date within the timeframes in § 147.116 by making a plan selection at the beginning of the enrollment period, but delays making a plan selection, consistent with § 147.116(a), coverage would begin the first day of the first month following the end of the waiting period, even if this would not be within the timeframes in § 147.116.

In addition to specifying that waiting periods in SHOPs would not exceed 60 days, proposed paragraph (g)(3) would also specify the calculation methodology for waiting periods in SHOPs. Under this proposed amendment, waiting periods in SHOPs would be calculated beginning on the date the employee becomes eligible—regardless of when the qualified employer notifies the SHOP about the newly qualified employee. For example, a 60-day waiting period would be calculated as the date an employee becomes otherwise eligible plus 59 days. Under this methodology, the date the employee becomes otherwise eligible counts as the first day of the waiting period. We propose this amendment to ensure that employers will remain in compliance with § 147.116 when factoring in certain aspects of the SHOP enrollment timeline, such as the 30 days employers would have under these proposed amendments to notify the SHOP about a newly qualified employee, the 30 days newly qualified employees have to make a plan selection, and the coverage effective dates that would apply under these proposed amendments to § 155.725(g). To minimize operational complexity in the Federal platform build for the SHOP, we are also proposing amendments to paragraph (g)(3) to specify that a Federally-facilitated SHOP or a State-based SHOP that uses the Federal platform for SHOP eligibility or enrollment functions would only allow waiting periods of 0, 15, 30, 45, and 60 days.

Nothing in this proposal would change the rule that in no case may the effective date for a newly qualified employee fail to comply with § 147.116. This proposal would not change § 147.116 and the proposals described in this section of the preamble apply only for purposes of the SHOPs.

We propose to amend paragraph (j)(2)(i) to reflect the proposed codification of existing special enrollment periods discussed in the preamble to § 155.420, specifically those proposed to be codified at § 155.420(d)(10), (11) and (12).

We seek comment on all aspects of these proposals.

8. SHOP Employer and Employee Eligibility Appeals Requirements (§ 155.740)

We propose to amend § 155.740(b)(2) to include a cross-reference to proposed § 155.505(h). This amendment would permit SHOP employer and employee eligibility appeals processes to use a secure and expedient paper-based process if the appeals entity cannot fulfill certain electronic requirements.

9. Request for Reconsideration (§ 155.1090)

We propose a new section § 155.1090 to allow an issuer to request reconsideration of denial of certification of a plan as a QHP for sale through an FFE. We propose that an issuer that has applied to an FFE for certification of QHPs and has been denied certification must submit to HHS a written request for reconsideration within 7 calendar days of the date of written notice of denial of certification in the form and manner specified by HHS in order to obtain a reconsideration. We further propose that the issuer must include any and all documentation in support of its request when it submits its request for reconsideration. We propose that requests may be submitted and considered only after an issuer has submitted a complete, initial application for certification and been denied. In § 155.1090(a)(3), we propose that HHS would provide the issuer with a written reconsideration decision, and that decision would constitute HHS's final determination. We believe this approach would afford issuers an opportunity to furnish any additional facts and information that might not have been considered as part of an FFE's initial decision to deny certification. We believe the short timeline is required to permit us to implement a decision to certify a plan following a request for reconsideration in time for open enrollment. We intend to provide future guidance on the form and manner by which issuers should submit requests for reconsideration. We intend for the Office of Personnel Management to maintain authority over reconsideration of applications from issuers to offer a multi-State plan. We invite comments on this reconsideration proposal.

I. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. General Provisions

a. FFE User Fee for the 2018 Benefit Year (§ 156.50)

Section 1311(d)(5)(A) of the Affordable Care Act permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. If a State does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the Affordable Care Act directs HHS to operate an Exchange within the State. Accordingly, at § 156.50(c), we specify that a participating issuer offering a plan through an FFE must remit a user fee to HHS each month that is equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE.

OMB Circular No. A–25R establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. As in benefit years 2014 to 2017, issuers seeking to participate in an FFE in benefit year 2018 will receive two special benefits not available to the general public: (1) The certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP. These special benefits are provided to participating issuers through the following Federal activities in connection with the operation of FFEs:

- Provision of consumer assistance tools.
- Consumer outreach and education.
- Management of a Navigator program.
- Regulation of agents and brokers.
- Eligibility determinations.
- Enrollment processes.
- Certification processes for QHPs (including ongoing compliance verification, recertification and decertification).
- Administration of a SHOP Exchange.

OMB Circular No. A–25R further states that user fee charges should generally be set at a level so that they are sufficient to recover the full cost to the Federal government of providing the service when the government is acting in its capacity as sovereign (as is the case when HHS operates an FFE). Accordingly, we propose to set the 2018 user fee rate for all participating FFE issuers at 3.5 percent. This user fee rate assessed on FFE issuers is the same as the 2014 through 2017 user fee rate. In addition, we intend to seek an exception from OMB Circular No. A–25R, which requires that the user fee charge be sufficient to recover the full cost to the Federal government of providing the special benefit. We seek this exception to ensure that the FFE can support many of the goals of the Affordable Care Act, including improving the health of the population, reducing health care costs, and providing access to health coverage, in cases where user fee collections do not cover the full cost of the special benefit. We seek comment on this proposal.

Additionally, we note that some commenters have suggested that the FFE would be able to increase enrollment by allocating more funds to outreach and education, or reallocating resources from other funding sources when available to pay for those expenses if necessary. We seek comment on how much funding to devote to outreach and education, the method to determine such funding, and the effectiveness of certain outreach investments to inform future FFE funding allocations. We also seek comment on whether HHS should expressly designate a specific portion or amount of the FFE user fee to be allocated directly to outreach and education activities, recognizing the need for HHS to continue to adequately fund other critical Exchange operations such as the call center, *HealthCare.gov*, and eligibility and enrollment activities.

State-based Exchanges on the Federal platform enter into a Federal platform agreement with HHS to leverage the systems established by the FFE to perform certain Exchange functions, and to enhance efficiency and coordination between State and Federal programs. Accordingly, in § 156.50(c)(2), we specify that an issuer offering a plan through an SBE–FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the sum of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for State-based Exchanges that use the Federal platform for the applicable benefit year, unless the State-based Exchange and HHS agree on an alternative mechanism to collect the funds. The functions provided to issuers in the SBE–FPs include the Federal Exchange information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs, as defined at section 1413(e) of the Affordable Care Act; and enrollment in QHPs under § 155.400. As previously discussed, OMB Circular No. A–25R establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. The user fee rate for SBE–FPs is calculated based on the proportion of FFE costs that are associated with the FFE information technology infrastructure, the consumer call center, and eligibility and enrollment services, and allocating a share of those costs to issuers in the relevant SBE–FPs. A significant portion of expenditures for FFE services are associated with the information technology, call center infrastructure, and eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs as defined at section 1413(e) of the Affordable Care Act, and personnel who perform the functions set forth in § 155.400 to facilitate enrollment in QHPs. Based on this methodology, we propose to charge issuers offering QHPs through an SBE–FP a user fee rate of 3.0 percent of the monthly premium charged by the issuer for each policy under a plan offered through an SBE–FP. This fee would recover funding to support FFE operations incurred by the Federal government associated with providing the services described above. We seek comment on this proposal. In the 2017 Payment Notice, we set the user fee rate for SBE–FPs at 1.5 percent of premiums charged, rather than the full rate of 3.0, in order to provide a transition year during which States could adjust to the assessment of a user fee in SBE–FP States. We seek comment on whether the impact of increasing the SBE–FP user fee rate to the full rate should be spread over one additional year.

We note that we intend to review the costs incurred to provide these special benefits each year, and revise the user fee rate for issuers in the FFEs and SBE–FPs accordingly in the annual HHS notice of benefit and payment parameters.

b. Single Risk Pool (§ 156.80)

Under § 156.80, an issuer must establish an index rate for each State market in the single risk pool. The index rate must be based on the total combined claims costs for providing essential health benefits within the single risk pool of that State market. The index rate also must be adjusted on a market-wide basis for the State based on the total expected market-wide payments and charges under the risk adjustment program and Exchange user fees. We propose to amend § 156.80(d) to remove the reference to the transitional reinsurance program, which was for benefit years 2014 through 2016.

As stated in the Unified Rate Review Instructions, calibration for age, geography, and tobacco use is permissible as long as the calibration is applied uniformly in the single risk pool. These calibration adjustments generally allow for the permissible rating factors under section 2701 of the PHS Act and 45 CFR 147.102 to be applied correctly to the issuer's plans. For example, we use the term "age calibration" to refer to an adjustment to the index rate, made uniformly for all plans in the risk pool, to reflect the fact that without calibration, the plan-adjusted index rate reflects the average age of the issuer's risk pool and the uniform age rating curve does not. Therefore, age calibration is necessary in order to correctly apply the age curve and calculate the premium rates. The same rationale applies when applying geographic and tobacco rating factors to the plan-adjusted index rate.

To more explicitly reflect how the rating factors under 45 CFR 147.102 and the index rating methodology under 45 CFR 156.80 work together, we propose to restructure paragraph (d)(1) as paragraphs (d)(1)(i) through (iv), adding new paragraph (d)(1)(iii) to provide that the index rate must be calibrated on a market-wide basis to correspond to an age rating factor of 1.0, a geographic rating factor of 1.0, and a tobacco rating factor of 1.0, in a manner specified by the Secretary in guidance. Because it is essentially an adjustment to the index rate, the calibration from the single risk pool index rate to the allowable rating factors may not vary by plan; it must be made uniformly for all plans in a State and market. We would provide detailed technical guidance through Unified Rate Review Instructions to ensure accurate and uniform application of the calibration methodology proposed here. We seek comment on this proposed codification.

2. Essential Health Benefits Package

a. Premium Adjustment Percentage (§ 156.130)

Section 1302(c)(4) of the Affordable Care Act directs the Secretary to determine an annual premium adjustment percentage, which is used to set the rate of increase for three parameters detailed in the Affordable Care Act: The maximum annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code, and the assessable payment amounts under section 4980H(a) and (b) of the Code. Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and that this percentage will be published annually in the HHS notice of benefit and payment parameters.

Under the methodology established in the 2015 Payment Notice and amended in the 2015 Market Standards Rule for estimating average per capita premium for purposes of calculating the premium adjustment percentage, the premium adjustment percentage is calculated based on the projections of average per enrollee employer-sponsored insurance premiums from the NHEA, which is calculated by the CMS Office of the Actuary. Accordingly, using the employer-sponsored insurance data, the premium adjustment percentage for 2018 is the percentage (if any) by which the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for 2017 ($5,962) exceeds the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for 2013 ($5,132).[51] Using this formula, the proposed premium adjustment percentage for 2018 is 16.17303196 percent. We note that the 2013 premium used for this calculation has been updated to reflect the latest NHEA data. Based on the proposed 2018 premium adjustment percentage, we propose the following cost-sharing parameters for calendar year 2018.

Maximum Annual Limitation on Cost Sharing for Calendar Year 2018. Under § 156.130(a)(2), for the 2018 calendar year, cost sharing for self-only coverage may not exceed the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage for 2018, and for other than self-only coverage, the limit is twice the dollar limit for self-only coverage. Under § 156.130(d), these amounts must be rounded down to the next lowest multiple of 50. Using the premium adjustment percentage of 16.17303196 percent for 2018 that we propose above, and the 2014 maximum annual limitation on cost sharing of $6,350 for self-only coverage, which was published by the IRS on May 2, 2013,[52] we propose that the 2018 maximum annual limitation on cost sharing would be $7,350 for self-only coverage and $14,700 for other than self-only coverage. This represents a 2.8 percent increase above the 2017 parameters of $7,150 for self-only coverage and $14,300 for other than self-only coverage.

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[51] *See* "NHE Projections 2015–2025—Tables" available at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html* in Tables 1 and 17. A detailed description of the NHE projection methodology is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf.*

b. Reduced Maximum Annual Limitation on Cost Sharing (§ 156.130)

Sections 1402(a) through (c) of the Affordable Care Act direct issuers to reduce cost sharing for essential health benefits for eligible individuals enrolled in a silver level QHP. In the 2014 Payment Notice, we established standards related to the provision of cost-sharing reductions. Specifically, in 45 CFR part 156, subpart E, we specified that QHP issuers must provide cost-sharing reductions by developing plan variations, which are separate cost-sharing structures for each eligibility category that change how the cost sharing required under the QHP is to be shared between the enrollee and the Federal government. At § 156.420(a), we detailed the structure of these plan variations and specified that QHP issuers must ensure that each silver plan variation has an annual limitation on cost sharing no greater than the applicable reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters. Although the amount of the reduction in the maximum annual limitation on cost sharing is specified in section 1402(c)(1)(A) of the Affordable Care Act, section 1402(c)(1)(B)(ii) of the Affordable Care Act states that the Secretary may adjust the cost-sharing limits to ensure that the resulting limits do not cause the AVs of the health plans to exceed the levels specified in section 1402(c)(1)(B)(i) of the Affordable Care Act (that is, 73 percent, 87 percent, or 94 percent, depending on the income of the enrollee). Accordingly, we propose to continue to use a method we established in the 2014 Payment Notice for determining the appropriate reductions in the maximum annual limitation on cost sharing for cost-sharing plan variations. As we proposed above, the 2018 maximum annual limitation on cost sharing would be $7,350 for self-only coverage and $14,700 for other than self-only group coverage. We analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute to determine whether to adjust the reductions so that the AV of a silver plan variation will not exceed the AV specified in the statute. Below, we describe our analysis for the 2018 benefit year and our proposed results.

Consistent with our analysis in the past four Payment Notices, we developed three test silver level QHPs, and analyzed the impact on AV of the reductions described in the Affordable Care Act to the estimated 2018 maximum annual limitation on cost sharing for self-only coverage ($7,350). The test plan designs are based on data collected for 2017 plan year QHP certification to ensure that they represent a range of plan designs that we expect issuers to offer at the silver level of coverage through the Exchanges. For 2018, the test silver level QHPs included a PPO with typical cost-sharing structure ($7,350 annual limitation on cost sharing, $2,215 deductible, and 20 percent in-network coinsurance rate), a PPO with a lower annual limitation on cost sharing ($4,950 annual limitation on cost sharing, $2,895 deductible, and 20 percent in-network coinsurance rate), and an HMO ($7,350 annual limitation on cost sharing, $3,375 deductible, 20 percent in-network coinsurance rate, and the following services with copayments that are not subject to the deductible or coinsurance: $500 inpatient stay per day, $350 emergency department visit, $25 primary care office visit, and $55 specialist office visit). All three test QHPs meet the AV requirements for silver level health plans.

We then entered these test plans into the proposed 2018 AV Calculator developed by HHS and observed how the reductions in the maximum annual limitation on cost sharing specified in the Affordable Care Act affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with a household income between 100 and 150 percent of the Federal poverty line (FPL) (⅔ reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of the FPL (⅔ reduction), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV level (94 and 87 percent, respectively). In contrast, the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with a household income between 200 and 250 percent of FPL (½ reduction), would cause the AVs of two of the test QHPs to exceed the specified AV level of 73 percent. As a result, we propose that the maximum annual limitation on cost sharing for enrollees in the 2018 benefit year with a household income between 200 and 250 percent of FPL be reduced by approximately ⅕, rather than ½, consistent with what we have proposed in previous years. This would allow issuers the flexibility in designing innovative plans with varying lower maximum annual limitation on cost sharing and deductibles for the 73 percent plans. We further propose that the maximum annual limitation on cost sharing for enrollees with a household income between 100 and 200 percent of the FPL be reduced by approximately ⅔, as specified in the statute, and as shown in Table 15. These proposed reductions in the maximum annual limitation on cost sharing should adequately account for unique plan designs that may not be captured by our three model QHPs. We also note that selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute would not reduce the benefit afforded to enrollees in aggregate because QHP issuers are required to further reduce their annual limitation on cost sharing, or reduce other types of cost sharing, if the required reduction does not cause the AV of the QHP to meet the specified level. We welcome comment on this analysis and the proposed reductions in the maximum annual limitation on cost sharing for 2018.

We note that for 2018, as described in § 156.135(d), States are permitted to submit for approval by HHS State-specific datasets for use as the standard population to calculate AV. The deadline for submitting a dataset for the 2018 plan year is September 1, 2016.[53]

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[52] *See http://www.irs.gov/pub/irs-drop/rp-13-25.pdf.*

[53] The annual deadline for submitting State specific data for the actuarial value calculator was announced August 15, 2014. See *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/final-state-avc-guidance.pdf.*

TABLE 15—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2018

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2018	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2018
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) (that is, 100–150 percent of FPL)	$2,450	$4,900
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) (that is, 150–200 percent of FPL)	2,450	4,900
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) (that is, 200–250 percent of FPL)	5,850	11,700

c. Levels of Coverage: Bronze Plans (§ 156.140)

Section 2707(a) of the PHS Act and section 1302 of the Affordable Care Act direct issuers of non-grandfathered health insurance in the individual and small group markets, including QHPs, to ensure that plans meet a level of coverage specified in section 1302(d)(1) of the Affordable Care Act. A plan's level of coverage, referred to as the plan's actuarial value, is determined on the basis of the essential health benefits provided to a standard population. Section 1302(d)(1) of the Affordable Care Act requires the level of coverage for a bronze plan to have an AV of 60 percent, a silver plan to have an AV of 70 percent; a gold plan to have an AV of 80 percent; and a platinum plan to have an AV of 90 percent. In addition, section 1302(d)(3) states that the Secretary is to develop guidelines to provide for a de minimis variation in the actuarial valuations used in determining the level of coverage of a plan to account for differences in actuarial estimates. Currently, § 156.140(c) permits a de minimis variation of +/−2 percentage points.[54]

All plans subject to the annual limitation on cost sharing at section 1302(c) of the Affordable Care Act have a minimum level of generosity that limits the lowest AV that a plan can achieve. For instance, a plan with a deductible of $7,350 that is equal to the annual limitation on cost sharing of $7,350 (which is the proposed 2018 annual limitation on cost sharing) with no services covered until the deductible and annual limitation on cost sharing are met, other than preventive services required to be covered without cost sharing under section 2713 of the PHS Act and 45 CFR 147.130, has an AV of 58.54 percent based on the draft 2018 AV Calculator. Because of the annual limitation on cost sharing, the AV for this type of plan is within the de minimis range of a bronze level of coverage. This type of plan does not have first dollar coverage (except for certain required preventive services), and is not a HDHP under 26 U.S.C. 223(c)(2) eligible for use with a health savings account because the annual limit on cost sharing under the plan is likely higher than the annual out of pocket expense limit for HDHPs for 2018. Furthermore, the bronze plan described above is less generous than a catastrophic plan, because a catastrophic plan is required by section 1302(e)(1)(B) of the Affordable Care Act and § 156.155(a)(4) to provide at least three primary care visits before reaching the deductible.

We note that in future recalibrations of the AV Calculator, if claims costs increase faster than the annual limitation on cost sharing, issuers' flexibility in designing different bronze plans may be reduced. In order to address this difficulty in designing bronze plans that are at least as generous as catastrophic plans and meet the AV requirements using future AV Calculators, we propose to permit a broader de minimis range for bronze plans. The purpose of the current de minimis variation of +/− 2 percentage points is to give issuers the flexibility to set cost-sharing rates while ensuring consumers can easily compare plans of similar generosity. Thus, the de minimis range is intended to allow plans to float within a reasonable range and is not intended to freeze plan designs, which could prevent innovation in the market. However, we do recognize the unique challenges that may be posed for bronze plan designs under future AV Calculators, and we therefore propose to amend § 156.140(c) to increase the allowable de minimis range for bronze plans under certain circumstances.

Outside of HDHPs, which have separate cost-sharing requirements, under future AV Calculators, if actuarial values increase significantly, bronze plans may be required to limit the services for which the plan pays before the deductible is reached. Enrollment data from the FFEs show that consumers have a preference for plans that cover and pay for services below the deductible. Because we believe that the Affordable Care Act did not intend for bronze plans to be less generous than catastrophic plans, which are required to provide at least three primary care visits before the deductible, we believe that it is important to allow bronze plans to retain at least one service before the deductible. Therefore, through our authority under section 1302(d)(3) of the Affordable Care Act, which directs the Secretary to develop guidelines to provide for a de minimis variance in the actuarial valuations used in determining the level of coverage of a plan to account for differences in actuarial estimates, and section 1321(a)(1)(A) and (D) of the Affordable Care Act, which allows the Secretary to issue regulations setting standards for meeting the requirements for the establishment and operation of Exchanges, as well as such other requirements as the Secretary determines appropriate, we propose to allow bronze plans that cover and pay for at least one major service before the deductible, other than preventive services (some of which are required by Federal laws and regulations to have zero cost sharing) to have an allowable variance in AV of −2 percentage points and +5 percentage points. The purpose of this proposal is to ensure flexibility in bronze plan designs—particularly, to permit the design of bronze plans that will satisfy AV requirements and still remain at least as generous as catastrophic plans.

We therefore propose that the major services covered and paid for by the plan before the deductible that trigger the increased de minimis range be similar in scope and magnitude to the three primary care visits before the deductible required under catastrophic coverage. To permit issuers the flexibility to address enrollees' varying health needs, we propose that the major services an issuer may elect to cover and pay for before the deductible in order to access the broader de minimis range be: Primary care visits; specialist visits; inpatient hospital services; generic, specialty, or preferred branded drugs; or emergency room services. We selected these services as they can be used by individuals with a wide variety of conditions and they have a significant AV impact. We solicit comments on this proposal and the proposed definition of major services, as well as comments on whether any of these major services should be excluded from the list or other major services should added to this list. We also solicit comments on whether major services should be defined based on all or some of the service inputs listed in the AV Calculator. This policy does not exempt issuers from their obligations to comply with mental health and substance use disorder parity requirements, including the rule that a deductible cannot be applied to mental health or substance use disorder benefits in a classification unless it is no more restrictive than the predominant deductible applicable to substantially all medical/surgical benefits in the same classification.

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[54] Under § 156.400, the de minimis variation for a silver plan variation means a single percentage point.

We also propose that the major service covered and paid for before the deductible must apply a reasonable cost-sharing rate to the service to ensure that the service is reasonably covered. We also solicit comments on what should be considered a reasonable cost-sharing rate for the major service. Lastly, to ensure that a bronze plan can be as least as generous as a catastrophic plan, we propose that a bronze plan with at least three primary care services under the deductible would qualify as having a major service under the deductible.

In addition to ensuring that bronze plans can remain at least as generous as catastrophic coverage, we believe it is important to ensure that bronze plans can remain eligible to be HDHPs that may be paired with a health savings account. Therefore, we propose that if a bronze plan meets the Federal requirements to be an HDHP, the allowable variation in AV for those plans is −2 percentage points and +5 percentage points. These HDHPs would not be required to cover at least one major service before the deductible, outside of certain preventive services, to meet the requirements for the extended bronze plan de minimis range, but instead, these plans would be required to meet the requirements to be a HDHP within the meaning of 26 U.S.C. 223(c)(2), including the annual out-of-pocket expense limit for HDHPs. We solicit comments on this proposal.

We also seek comment on the proposed size of the de minimis range, which is proposed as −2 percentage points and +5 percentage points, and whether the +5 percentage points should be higher or lower. Based on our initial analysis of 2017 bronze plans submitted for QHP certification in the FFEs, most 2017 bronze plans are either HDHPs or are plans providing one of the major services defined above before deductible. We believe that this policy will not be disruptive to the current bronze plan market as it will allow more flexibility in designing bronze plans within the increased de minimis range as well as allow more options for issuers to leave 2017 cost-sharing structures unchanged.

In connection with the release of the proposed 2018 Payment Notice, we are also releasing the draft versions of the 2018 AV Calculator, including the 2018 AV Calculator Methodology and User Guide, for comment on the Center for Consumer Information and Insurance Oversight Web site.[55] As part of the draft 2018 AV Calculator, we added the option to calculate AV for a bronze plan with an extended de minimis range to align with this proposed policy. (We note that under this option, the AV Calculator will not automatically flag a plan in the bronze extended de minimis range that does not comply with the requirement to cover one major service before the deductible.) Our intention will be to align the final 2018 AV Calculator with any provisions that are finalized through this rulemaking.

d. Application to Stand-Alone Dental Plans Inside the Exchange (§ 156.150)

In the 2017 Payment Notice, we finalized § 156.150(a), which establishes a formula to increase the annual limitation on cost sharing for stand-alone dental plans. Specifically, we finalized that for plan years beginning after 2017, the annual limitation for an SADP for one covered child is $350 increased by the percentage increase of the consumer price index (CPI) for dental services for the year two years prior to the applicable plan year over the CPI for dental services for 2016; and, the annual limitation for an SADP for two or more covered children is twice that.

The formula increases the dollar limit for one covered child (currently set at $350) by the percentage increase of the CPI for dental services for the year two years prior to the applicable plan year over the CPI for 2016. For plan year 2018, the percentage increase of the CPI for dental services for the two years prior to the applicable plan year would be equal to the CPI for 2016, resulting in a zero percent increase for plan year 2018. Therefore, for plan year 2018, the dental annual limitation on cost sharing would be $350 for one child and $700 for one or more children. The annual limitation on cost sharing for plan year 2019 will be addressed in the annual HHS notice of benefit and payment parameters for the 2019 benefit year.

3. Qualified Health Plan Minimum Certification Standards

a. QHP Issuer Participation Standards (§ 156.200)

Section 156.200(c)(1) implements section 1301(a)(1)(C)(ii) of the Affordable Care Act to require as part of QHP participation standards that each QHP issuer offer at least one QHP in the silver coverage level and at least one QHP in the gold coverage level.

As evidenced by QHP application submissions to the FFEs, QHP issuers have generally interpreted this requirement to apply at the service area level, as opposed to at the Exchange level, meaning that an issuer must offer at least one QHP in the silver coverage level and at least one QHP in the gold coverage level throughout each service area in which it will offer a QHP through the Exchange (that is, one QHP that has an AV of 70 percent and one QHP that has an AV of 80 percent, plus or minus two percentage points). If the requirement were to be interpreted at the Exchange level, a QHP issuer could be in technical compliance with the requirement by offering one QHP in the silver coverage level and at least one QHP in the gold coverage level in a very limited service area, and not offer such coverage through the Exchange in a meaningful way. We believe that the Affordable Care Act did not intend to allow an issuer to offer a silver and gold QHP through the Exchange in merely one service area in a State, while offering other products through the Exchange, such as bronze or catastrophic QHPs, in other service areas. The proposal seeks to eliminate the possibility of such gaming. Provisions of the Affordable Care Act sought to ensure an adequate choice of QHPs and coverage to consumers. We are proposing this change to ensure that consumers have an adequate choice of QHPs at different coverage levels. Further, the Affordable Care Act also assumed calculation of the advance payment of the premium tax credit based on the availability of a second lowest cost silver plan. As such, we propose to modify our regulations to more accurately align with QHP issuer practice and our interpretation of the intention of the Affordable Care Act.

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[55] The draft 2018 AV Calculator and Methodology will be posted under the "Plan Management" section of CCIIO's Web site at: *https://www.cms.gov/cciio/resources/regulations-and-guidance/index.html.*

Section 1311(c)(1) and 1321(a)(1)(A) and (B) of the Affordable Care Act provide the Secretary of HHS with the authority to establish certification criteria for QHPs and Exchanges. Therefore, we are proposing to require QHP issuers to offer at least one silver and one gold coverage level QHP through the Exchange throughout each service area in which the issuer offers coverage through the Exchange. The offering of both silver and gold level QHPs is important to ensure adequate choice to Exchange consumers, as well as to ensure that a second lowest cost silver plan is available for calculating advance payments of the premium tax credit for consumers. We further clarify that an issuer can meet this standard by offering a multi-State plan in both silver coverage and gold coverage levels throughout each service area in which it offers other QHPs through an Exchange. We seek to establish this policy by proposing amendments to existing paragraph (c)(1).

Specifically, we propose to amend paragraph (c)(1) to require a QHP issuer to offer through the Exchange at least one QHP in the silver coverage level and at least one QHP in the gold coverage level, as described in § 156.140, throughout each service area in which it offers coverage through the Exchange. This added specificity will ensure that issuers applying for certification of their QHPs offer a silver and gold plan throughout each service area in which they offer coverage through the Exchange.

In the 2014 Payment Notice, in order to help ensure that qualified employers and qualified employees enrolling through an FF–SHOP are offered a robust set of QHP choices, we finalized a policy at § 156.200(g) under which an individual market FFE will certify a QHP only if the QHP issuer (or an issuer in the same issuer group) offers through the FF–SHOP of the State at least one QHP in the silver coverage level and at least one QHP in the gold coverage level, unless no issuer in the issuer group has at least a 20 percent share of the small group market share in the State, based on earned premiums. This policy is intended to leverage issuers' participation in the FFEs to promote fuller issuer participation in the FF–SHOPs, particularly in the initial years of the FF–SHOPs. We indicated in the preamble of the 2014 Payment Notice, in response to a commenter who suggested we reevaluate the policy in two years, that we would evaluate the effectiveness of the tying provision on an ongoing basis.

We now seek comment, based on feedback from stakeholders, on whether the policy at § 156.200(g) is still necessary or appropriate in the FF–SHOPs. We did not finalize this policy to apply to State-based SHOPs, nor are we aware of any State-based SHOPs that have implemented a similar policy. We are also cognizant that the policy may be discouraging issuer participation on the individual market FFEs. We therefore seek comment on whether we should eliminate this policy for the FF–SHOPs, for plan years beginning on or after January 1, 2018.

We recognize that eliminating the SHOP participation provision could have the effect of reducing FF–SHOP issuer participation in States, and seek comment on the implications for small businesses and how to accommodate such an effect. For example, in such a circumstance, in consideration of the ongoing investments that would be required to maintain the FF–SHOPs, including for premium aggregation services, we are considering providing for elimination of enrollment through FF–SHOP Web sites and providing for alternative means of enrollment into SHOP QHPs, either in States that would be particularly affected by this change or in all FF–SHOPs. An FF–SHOP Web site would still be maintained, consistent with section 1311(d)(4)(C) of the Affordable Care Act, but would not support online enrollment, except perhaps for the continuation of services for existing groups in the FF–SHOP through the end of any plan year that began before January 1, 2018. In addition, we seek comment on how entities such as web-brokers or third party administrators could help to facilitate enrollment in available SHOP QHPs. We seek comment on what other regulatory provisions would need to be modified or eliminated in such a circumstance, and on whether provisions relating to the operation of enrollment through a SHOP Web site should generally be optional at the election of the Exchanges, including State-based SHOPs.

b. Network Adequacy Standards (§ 156.230)

At § 156.230, we established the minimum criteria for network adequacy that issuers must meet to have plans certified as QHPs, including SADPs, in accordance with the Secretary's authority in section 1311(c)(1)(B) of the Affordable Care Act. Included at § 156.230(a)(2) is the requirement that all issuers maintain a network that is sufficient in number and types of providers to assure that all services will be accessible without unreasonable delay. Section 156.230(b) sets forth standards for access to provider directories requiring issuers to publish an up-to-date, accurate, and complete provider directory for plan years beginning on or after January 1, 2016.

In the 2017 Payment Notice, HHS finalized a policy to provide information about QHP network breadth on *HealthCare.gov* in order to assist consumers with plan selection. For the 2017 benefit year, we intend to pilot a network breadth indicator in certain States on *HealthCare.gov* to denote a QHP's relative network coverage.[56] HHS will make this network breadth classification available to consumers in those States at the point of plan comparison. The results of the pilot will determine if HHS expands the pilot to more States for 2018. The specifics of how the network breadth indicator is calculated are described in the Final 2017 Letter to Issuers in the Federally-facilitated Marketplaces.[57]

For the 2018 plan year, HHS is considering whether to incorporate more specificity into these indicators, and, in particular, how to identify for consumers whether a particular plan is offered as part of an integrated delivery system. For integrated delivery systems, the breadth of the network for a plan as calculated through the network breadth methodology may not accurately describe the ability of a consumer to access providers relative to consumers enrolled in plans that are not part of an integrated delivery system in the same county. We propose to incorporate this specificity into the network information displayed for plan year 2018 in all States where network breadth is displayed in 2018.

To define which plans utilize an integrated delivery system, we propose to use the alternate essential community provider standard in 45 CFR 156.235(b). Thus, we would identify a plan as part of an integrated delivery system if it provides a majority of covered professional services through physicians employed by the issuer, or through a single contracted medical group. If HHS finalizes this policy, we would provide additional details in the 2018 Letter to

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[56] Network Breadth Pilot (August 19, 2016), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Network-Classification-Pilot-Guidance-81916.pdf.*

[57] Final 2017 Letter to Issuers in the Federally facilitated Marketplaces (Feb. 29, 2016) *available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf.*

Issuers in the Federally-facilitated Marketplace.

We seek comment on all aspects of this proposal. In particular, we seek comment on whether we should make such a differentiation, and how best to indicate that a plan has an integrated delivery system—including on whether we should provide additional explanatory text to the current indicator that the plan receives, or whether we should establish a separate indicator. We seek comment on what words to use in either case to best convey the value of this classification to consumers. We also seek comment on our proposal to identify integrated delivery systems by using the alternate essential community provider standard, and whether there are plans that would not meet this definition but are best categorized in this group; and, if there is a continuum of plan arrangements to consider with respect to network integration, how best to classify those plans and provide that information to consumers.

Also, as a reminder, the requirement established in the 2017 Payment Notice at § 156.230(e) that QHP issuers count an essential health benefit provided by an out-of-network ancillary provider at an in-network facility towards the in-network annual limitation on cost sharing for QHPs in certain circumstances begins applying in benefit year 2018. That is, if a QHP enrollee received an EHB in an in-network setting, such as an in-network hospital, but as part of the provision of the EHB the enrollee was charged out-of-network cost sharing for an EHB provided by an out-of-network ancillary provider, that cost sharing would apply towards the annual limitation on cost sharing.

Alternatively, the plan could provide a written notice to the enrollee by the longer of when the issuer would typically respond to a timely submitted prior authorization request, or 48 hours before the provision of the benefit. The written notice would state that additional costs may be incurred for the EHB provided by an out-of-network ancillary provider in an in-network setting, including balance billing charges, unless such costs are prohibited under State law; and that any additional charges may not count toward the in-network annual limitation on cost sharing. This alternative would not be available if the issuer does not meet the timeframe established in regulation. We are proposing that this policy applies to QHPs, both on and off Exchanges, regardless of whether the QHP covers out-of-network services, and seek comment on other policy changes that could limit ''surprise bills'' for consumers. As stated in the 2017 Payment Notice, we intend to continue to monitor these situations, including issuers' timely compliance with this provision, to consider whether further rulemaking is needed.

c. Essential Community Providers (§ 156.235)

In the 2017 Payment Notice, we finalized that, for QHP certification cycles beginning with the 2018 benefit year, HHS would credit issuers for multiple contracted or employed full-time equivalent (FTE) practitioners at a single location, up to the number of available FTE practitioners reported to HHS by the essential community provider (ECP) facility through the ECP petition process and published on the HHS ECP list. As HHS conducts additional provider outreach to collect provider data necessary to implement a methodology that would credit issuers for multiple contracted or employed full-time equivalent practitioners at a single location, we propose in § 156.235(a)(2)(i) to continue the 2017 benefit year calculation methodology that a plan applying for QHP certification to be offered through a Federally-facilitated Exchange must demonstrate in its QHP application that its network includes as participating providers at least a minimum percentage, as specified by HHS, of available ECPs in each plan's service area, with multiple providers at a single location counting as a single ECP toward both the available ECPs in the plan's service area and the issuer's satisfaction of the ECP participation standard. Similarly, in § 156.235(b)(2)(i), we propose to continue the 2017 benefit year calculation methodology that a plan described in § 156.235(a)(5) applying for QHP certification to be offered through a Federally-facilitated Exchange demonstrate in its QHP application that the number of its providers that are located in Health Professional Shortage Areas or five-digit zip codes in which 30 percent or more of the population falls below 200 percent of the Federal Poverty Line satisfies a minimum percentage, specified by HHS, of available ECPs in the plan's service area with multiple providers at a single location counting as a single ECP. We seek comment on these proposals. We are also considering changes to the counting of hospital ECPs for the 2019 benefit year and seek comment on the best approach for measuring hospital participation.

d. Enrollment Process for Qualified Individuals (§ 156.265)

We propose an amendment to § 156.265 requiring differential display of standardized options. A discussion of the proposed provision is contained in the preamble discussion regarding § 155.220, which concerns standards for agents and brokers using the direct enrollment process.

We solicit comments on this proposal.

e. Issuer Participation for the Full Plan Year (§ 156.272)

We propose adding § 156.272 to provide as a condition of certification that QHP issuers in all individual market Exchanges must make their QHPs available for enrollment through the Exchange for the full plan year for which the plan was certified, unless a basis for suppression under § 156.815 applies. We also propose that issuers in all SHOP Exchanges must make their QHPs available for enrollment through the SHOP Exchange for the full plan year for which the plan was certified, unless a basis for suppression under § 156.815 applies. This requirement would ensure that consumers enrolling in the individual market during limited open enrollment periods have the same plan choice as those who enrolled during open enrollment, and that qualified employers and qualified employees would have generally consistent plan choices throughout the plan year.

If this proposal is finalized, under our existing civil money penalty authority at § 156.805(a)(1), QHP issuers in FFEs and FF–SHOPs that do not comply with § 156.272(a) and (b) could be subject to CMPs. (Issuers would not be subject to CMPs if a basis for suppression under § 156.815 applies.) We also propose at § 156.272(c) that if an issuer fails to comply with those sections, HHS could, at its discretion, preclude that issuer from participating in the FFEs and FF–SHOPs, for up to the two succeeding years.

We seek comments on this proposal, including the applicability of this section to all Exchanges and the potential use of CMPs for QHP issuers in the FFEs and FF–SHOPs.

f. Non-Certification and Decertification of QHPs (§ 156.290)

Currently, under § 156.290(b), when a QHP issuer elects to not seek certification for a subsequent, consecutive certification cycle with the Exchange, it is required to provide notification to enrollees. However, a QHP issuer is not required to provide notification to enrollees when it seeks but is denied certification for a subsequent, consecutive certification cycle by the Exchange. We propose to require that QHP issuers provide such notice within 30 days of the date of an Exchange's denial of certification for a subsequent, consecutive certification cycle. Requiring notice in a timely manner would allow enrollees to be prepared to participate in the upcoming open enrollment period. We also propose to amend the section title from Non-renewal and decertification of QHPs to Non-certification and Decertification of QHPs, and revise the paragraph headings for § 156.290(a) and (b) to reflect that QHPs are certified on an annual basis rather than renewed. We seek comment on these proposals.

g. Other Considerations

Increasingly, the Exchanges serve as laboratories for innovations through which QHPs develop new ways to provide quality, cost-effective health care that responds to consumers' preferences and needs. We have heard from issuers about innovations around paying for high-quality care, working with health care professionals to encourage coordinated care, standardizing benefits in ways that promote high-value care, and using data analytics to engage with consumers in creative ways that improve their health and bolster retention. We also continue to seek to foster market-driven programs in the Exchanges that can improve the management of costs and care, and that provide consumers with quality, person-centered coverage. As we stated in the 2017 Payment Notice, we believe that innovative issuer, provider, Exchange, and local programs or strategies can successfully promote and manage care, in a manner that contributes to better health outcomes and lower rates while creating important differentiation opportunities for market participants. We seek comment on ways in which we can facilitate such innovation, and in particular on whether there are regulations or policies in place that we should modify for 2018 in order to better meet the goals of affordability, quality, and access to care.

4. Eligibility and Enrollment Standards for Qualified Health Plan Issuers on State-Based Exchanges on the Federal Platform (§ 156.350)

In the 2017 Payment Notice we established, in § 156.350, that in order to participate in an SBE–FP, a QHP issuer must comply with HHS regulations and guidance pertaining to issuer eligibility and enrollment functions as if the issuer were an issuer of a QHP in an FFE. These regulations and guidance include those requirements specified in paragraphs (a)(1) through (3) of § 156.350, which currently include § 156.285(c)(8)(iii). For the same reasons that we propose to add new paragraph § 155.200(f)(4), we also propose to amend paragraph § 156.350(a)(2) to specify that, in order to participate in an SBE–FP using the Federal platform for SHOP enrollment functions, a QHP issuer would be required to send enrollment reconciliation files on at least a monthly basis according to a process, timeline, and file format established by the FF–SHOPs, consistent with § 156.285(c)(5). Issuers in States operating an SBE–FP for SHOP enrollment functions would be required to follow the process applicable in the FF–SHOPs, as described in § 156.285(c)(5). This amendment would become effective with the effective date of the final rule. We seek comment on this proposal.

5. Reconciliation of the Cost-Sharing Reduction Portion of Advance Payments Discrepancies and Appeals (§ 156.430(h))

As implemented in the regulations at 45 CFR 156.430, HHS reconciles the cost-sharing reduction portion of advance payment amounts by comparing what the enrollee in a cost-sharing reduction plan variation actually paid in cost sharing to what the enrollee would have paid if enrolled in a standard plan. In order to facilitate reconciliation of the cost-sharing reduction portion of advance payments to the actual amount provided for enrollees in cost-sharing reduction variation plans, issuers must report the amount they paid for each eligible medical claim, the amount enrollees paid for the claims, and the amount of cost sharing that would have been paid for the same services under the corresponding standard plan. This information is used to reconcile the actual cost-sharing amounts provided for each policy in a plan variation to the estimated payments that the issuer had been paid in advance. As set forth at § 156.410(d)(3), issuers are not reimbursed for any cost-sharing reductions provided to enrollees who were erroneously assigned to a plan variation more generous than the one for which they are eligible. As set forth at § 155.430(d)(4), any cost-sharing reductions, to the extent thereby or otherwise erroneously provided (such as cost-sharing reductions for non-EHB or non-covered services or cost-sharing reductions provided after a policy has been terminated) must be excluded from the reconciliation process.

In order to ensure the integrity of reconciliation of the cost-sharing reduction portion of advance payments for the 2014 and 2015 benefit years, we implemented automatic system checks that validated data at the time of data submission, for example matching QHP or subscriber IDs to HHS data for a benefit year, and verifying the issuer used the applicable methodology and submitted applicable attestations. This resulted in the rejection of some cost-sharing reduction amounts submitted by issuers. Additionally, some issuers were unable to prepare complete data files in time to meet the cost-sharing reduction data submission deadline. In order to provide issuers with an opportunity to address potential errors that would have directly impacted the calculation of their reconciled cost-sharing reduction amounts, HHS implemented a process for reporting data discrepancies for the 2014 and 2015 benefit year.[58]

We propose adding new paragraph (h)(1) to § 156.430 to require that any issuer that reports a discrepancy and seeks to dispute the notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments, in the manner set forth by HHS, must report the discrepancy to HHS within 30 calendar days of notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments as described in § 156.430(e).

We further propose to codify in § 156.430(h)(2) that an issuer may appeal the amount of reconciliation of the cost-sharing reduction portion of advance payments, under the process set forth in § 156.1220 of this subchapter, only if it has submitted a discrepancy report for its cost-sharing reduction reconciled amounts for the applicable benefit year. We note that irrespective of whether an issuer has filed a discrepancy report under § 156.430, a request for reconsideration under § 156.1220 may only be filed to contest a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error, as required under § 156.1220.

We seek comment on these proposals.

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[58] On June 23, 2016 CMS released FAQs and technical specifications on the discrepancy resolution process for issuers to follow to report a discrepancy related to reconciliation of the cost-sharing reduction portion of advance payments. The technical specifications are available on the Center for Consumer Information and Insurance Oversight Web site: *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Cost-Sharing-Reduction-Reconciliation-Discrepancy-Resolution-Inbound-Specification.pdf.*

6. Compliance Reviews of QHP Issuers in Federally-Facilitated Exchanges (§ 156.715)

At § 156.715, we previously established that a QHP issuer is subject to compliance reviews to ensure ongoing compliance with Exchange requirements and standards. In § 156.715(b), we require QHP issuers to make available to HHS records that pertain to their activities in an FFE. In the first few years of FFE operations, the vast majority of QHP issuers were responsive and cooperative with the compliance reviews. QHP issuers generally submitted requested documents on time and were responsive to requests for additional information. However, a few QHP issuers were less responsive to HHS, which resulted in unnecessary delays of the compliance reviews. We propose to amend this section to specify HHS's authority to impose remedies authorized under subpart I of part 156 in situations where the QHP issuer is non-responsive or uncooperative with the compliance reviews authorized under this section.

7. Qualified Health Plan Issuer Responsibilities

a. Administrative Appeals (§ 156.1220)

As discussed in the preamble to § 153.630, we propose adding paragraphs (a)(1)(vii) and (viii) to § 156.1220, providing an administrative appeals right to issuers to contest only a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error with respect to the findings of a second validation audit as a result of risk adjustment data validation; or the calculation of a risk score error rate as a result of risk adjustment data validation, respectively. Also as discussed in the preamble to §§ 153.630 and 156.430(h), we propose requiring issuers to file a report for discrepancies related to risk adjustment data validation and discrepancies related the reconciliation of the cost-sharing reduction portion of advance payments, if the issue is identifiable, prior to filing a request for reconsideration as set forth at § 156.1220. As such, we propose to amend § 156.1220(a)(4)(ii), to provide that, notwithstanding § 156.1220(a)(1), a reconsideration with respect to a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error may be requested only if, to the extent the issue could have been previously identified, the issuer notified HHS of the dispute through the applicable process for reporting a discrepancy set forth in § 153.630(d)(2), § 153.710(d)(2), or § 156.430(h)(1), and the dispute has not been resolved.

Because risk adjustment payments and charges for the 2015 benefit year will not be adjusted as a result of the risk adjustment data validation process, we do not believe an administrative appeal right is necessary for the 2015 benefit year. Therefore, we propose that the first year of risk adjustment data validation appeals would begin with the 2016 benefit year, which is the first year that risk adjustment data validation will affect the amount of risk adjustment payments and charges. As such, we propose to limit the proposed new § 156.1220(a)(1)(vii) and (viii) (specifying that an issuer may file a request for reconsideration under this section to contest a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error, with respect to the findings of a second validation audit or the calculation of a risk score error rate as a result of risk adjustment data validation) to administrative appeals with respect to risk adjustment data for the 2016 benefit year and beyond.

We propose to amend § 156.1220(a)(2) regarding the materiality threshold for filing a request for reconsideration to include a reference to the administrative appeals related to the risk adjustment data validation process. We also propose to amend § 156.1220(a)(3)(ii) to add a reference to risk adjustment data validation and to provide that issuers have 30 calendar days to request reconsideration from the date of the notification of the findings of a second validation audit and the calculation of a risk score error rate as a result of risk adjustment data validation. We believe 30 calendar days is sufficient for issuers to review the findings of a second validation audit or the calculation of a risk score error rate as a result of risk adjustment data validation and to submit a request for reconsideration. We seek comment on these timeframes and the appeal proposal.

b. Direct Enrollment With the QHP Issuer in a Manner Considered To Be Through the Exchange (§ 156.1230)

In this rule, we proposed a number of modifications and new requirements in § 155.220 which would apply to web-brokers using the direct enrollment channel. We propose to add a number of these standards to §§ 156.265 and 156.1230(b) so that they also apply to issuers using direct enrollment on a Federally-facilitated Exchange. Specifically, in § 156.1230, we propose to: (1) Specify that HHS may immediately suspend the QHP issuer's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS's satisfaction; (2) require QHP issuers to demonstrate operational readiness and compliance with applicable requirements prior to their Web sites being used to complete QHP selections; and (3) require QHP issuers to provide consumers with correct information regarding FFEs, QHPs offered through the FFEs and insurance affordability programs, and refrain from marketing or conduct that is misleading, coercive, or discriminatory. A more detailed discussion of these proposed provisions is contained in the preamble discussion regarding § 155.220.

We solicit comments on these proposals and specifically seek comment on whether direct enrollment with a QHP issuer should be permitted for enrollments through all SBE–FPs, or at the option of SBE–FPs.

c. Other Notices (§ 156.1256)

Section 156.1256 requires health insurance issuers offering coverage through an FFE or an SBE–FP to notify enrollees of material plan or benefit display errors under certain circumstances. We propose to change the paragraph cross-referenced in § 156.1256 from § 155.420(d)(4) to § 155.420(d)(12) to reflect our proposal to codify in § 155.420(d)(12) the special enrollment period for material plan or benefit display errors. Since the noticing requirement in § 156.1256 is limited to material plan or benefit display errors and resulting special enrollment periods, proposed § 155.420(d)(12) is a more appropriate reference for this section. We also propose to make some minor non-substantive changes to the regulation text. We seek comments on this proposal.

J. Part 157—Employer Interactions With Exchanges and Shop Participation

For a discussion of the provisions of this proposed rule related to part 157, please see the preamble to § 155.725.

K. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Newer Experience (§ 158.121)

a. Deferred Reporting of Newer Business

Section 2718(c) of the PHS Act provides that, subject to the certification of the Secretary, the NAIC is to establish standardized medical loss ratio methodologies that take into consideration (among other things) the special circumstances of newer plans. Consistent with the NAIC's recommendation to HHS,[59] the MLR December 1, 2010 interim final rule (75 FR 74863) allows issuers to defer reporting of experience of policies newly issued and with fewer than 12 months of experience until the following reporting year, if such policies contribute to 50 percent or more of the issuer's total earned premium for the MLR reporting year. As explained in the interim final rule, the rationale for deferring experience of newly issued policies is that claims experience can be substantially lower than the premium revenue from those policies during the year in which the coverage is issued (although this may occur to a lesser extent in the current environment than prior to introduction of the Affordable Care Act market reforms), and could create a barrier to the entry of new issuers into a market.

However, the NAIC's recommendation was developed in 2010, prior to implementation of many Affordable Care Act market reforms. As a result, the current MLR regulation allows issuers to defer reporting the experience of new policies that were in effect for *fewer than* 12 months, but not for those in effect for the *full* 12 months. This limitation does not account for the fact that beginning in 2014, issuers of non-grandfathered health insurance coverage in the individual and small group markets generally must offer coverage for a consecutive 12-month period (which may be on a calendar year basis or otherwise). Consequently, issuers entering these markets in substantial part in 2014 or later whose policies contribute to 50 percent or more of the issuer's total earned premium for the MLR reporting year are unable to defer reporting of this new business for MLR purposes because such coverage has a full 12 months of experience. Therefore, to align MLR reporting with the requirement that non-grandfathered coverage generally must provide coverage for a consecutive 12-month period, we propose to modify § 158.121 to allow issuers to defer, for MLR purposes, reporting of data for newer experience if 50 percent or more of the issuer's total earned premium for the MLR reporting year is attributable to newly issued policies with 12 full months of experience, rather than policies with less than 12 months of experience. We seek comments on this proposal.

2. Rebating Premium if the Applicable Medical Loss Ratio Standard Is Not Met (§§ 158.232, 158.240)

a. Limit on Rebate Liability

Section 2718(b)(1)(B)(ii) of the PHS Act requires, beginning on January 1, 2014, the MLR to be calculated as an average of 3 consecutive years of experience. When an established issuer's MLR falls below the applicable MLR standard in a given year, the 3-year averaging spreads the actual payment of the rebate over the period of 3 years. This allows issuers to offset low and high MLRs within any 3-year period, enabling issuers to potentially pay a lower overall rebate. However, issuers that newly enter the market in 2014 or later are only able to calculate their first two MLRs based on 1 or 2 years of experience. Consequently, the experience of the first 1 or 2 years can have a disproportionate and overlapping impact on such issuers' average MLRs in their first 3 years in the market, and the 3-year averaging required by section 2718(b)(1)(B)(ii) can lead to distorted MLR calculations and could be a barrier to the entry of new issuers into a market. As a result of the 3-year averaging rule, a new issuer that has an MLR that is initially low but increases within the first 3 years in the market may end up paying a higher total rebate over those initial 3 years than an established issuer with stable enrollment with the same experience in each of those 3 years. In addition, the 3-year averaging rule can have a similar impact on an established issuer that rapidly and significantly expands its presence in the market.

We note that only a narrow subset of issuers are affected in this way by 3-year averaging: Specifically, new issuers and established issuers that experience rapid growth (either by entering a new market or rapidly and significantly expanding their presence in an existing market) and whose MLR falls below the standard in one year and increases within the following 2 years.

Consistent with the requirement under section 2718(c) of the PHS Act to design standardized MLR methodologies that take into consideration (among other things) the special circumstances of smaller and newer plans, we propose to amend §§ 158.240 and 158.232 to mitigate the impact of 3-year averaging on these issuers and thereby reduce barriers to entry and promote competition in health insurance markets. Specifically, we propose to modify § 158.240 by adding a new paragraph (d) and redesignating the existing paragraphs (d) and (e) as paragraphs (e) and (f), respectively, to provide flexibility to limit in appropriate cases an issuer's total rebate liability payable with respect to a given calendar year. We also propose conforming amendments to paragraph (c) to recognize the proposed new flexibility under new paragraph (d). Under this proposal, if an issuer elects this flexibility, the maximum single-year rebate liability attributable to a given calendar year would be limited to no more than the amount determined based on the issuer's MLR calculated using only that year's experience. In these circumstances, we propose to adjust the maximum rebate liability attributable to a given calendar year in each of the two subsequent reporting years to reflect restatement of claims incurred in that calendar year as of March 31 following each of those 2 subsequent reporting years. The restatement of incurred claims would ensure that the rebate liability with respect to the calendar year in question is corrected either upward or downward, as appropriate, in the two subsequent years in order to implement the 3-year averaging requirement. Similarly, we propose that an issuer that elects this option would have to adjust the maximum rebate liability attributable to a given calendar year in the 2 subsequent reporting years to reflect the credibility adjustment applicable in each of those 2 subsequent reporting years. That is, the rebate liability attributable to year 1 would be recalculated in year 2 using a credibility adjustment based on the sum of life-years for years 1 and 2. This approach is consistent with the manner in which the credibility adjustment was applied with respect to all issuers when the MLR requirements were first implemented. We seek comments on this proposal.

We also propose that for an issuer that elects this option, for each reporting year, after the issuer recalculates the maximum rebate liability with respect to each calendar year in the aggregation using restated incurred claims and updated credibility adjustment (as applicable), the outstanding rebate liability with respect to each year in the aggregation would be determined by reducing the maximum rebate liability with respect to that year by any rebate payments made toward it in the two prior years (as applicable). Any rebate payable for a given reporting year would be applied toward the outstanding rebate liability of the earliest year in the relevant aggregation first. If the rebate calculated for the reporting year based on a multi-year average MLR (2- or 3-year average, as applicable) exceeds the combined outstanding rebate liability for all calendar years included in the aggregation, then under our proposal, the actual rebate payable by the issuer for that reporting year would be limited to the amount of the combined outstanding rebate liability. Conversely, if the total rebate calculated for the reporting year based on a multi-year average MLR is lower than the combined outstanding rebate liability for all years included in the aggregation, then we propose that the actual rebate payable by the issuer for that reporting year be limited to the amount calculated for the reporting year based on a multi-year average MLR. Therefore, our proposal would generally prevent the total rebate amount paid by an issuer with respect to any given calendar year over the course of 3 consecutive years from exceeding the rebate amount resulting from the ratio of the issuer's incurred claims and quality improvement activity expenses to the issuer's after-tax earned premium for that calendar year, with applicable adjustments, falling below the applicable MLR standard. At the same time, our proposal is designed to benefit only new issuers and established issuers that experience rapid growth whose MLR falls below the standard in one year and increases within the following 2 years. This is because the combined outstanding rebate liability for all years included in the aggregation will generally equal or exceed the rebate calculated for the reporting year based on a 3-year average MLR for established issuers that do not experience rapid growth. Therefore, our proposed limit on the rebate liability would not benefit such issuers.

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[59] National Association of Insurance Commissioners—Model Regulation Service, Regulation for Uniform Definitions and Standardized Methodologies for Calculation of the Medical Loss Ratio for Plan Years 2011, 2012 and 2013 per Section 2718(b) of the Public Health Service Act (Oct 27, 2010), *available athttp://www.naic.org/documents/committees_ex_mlr_reg_asadopted.pdf.*

For a simplified illustration of our proposal, suppose that a new, fully-credible individual market issuer reports year 1 incurred claims and quality improvement activity expenses (QIA) of $500,000 and premium adjusted for applicable taxes and fees of $1,000,000 (and no other relevant revenue or expenses relevant to the MLR calculation); year 2 incurred claims and QIA of $700,000 and after-tax premium of $1,000,000; and incurred claims and QIA of $800,000 and after-tax premium of $1,000,000 thereafter. Under our proposal, the rebate liability for year 1 would be calculated as (80% − $500,000/$1,000,000) * $1,000,000 = $300,000; and the issuer would consequently pay a $300,000 rebate for year 1. Suppose that after year 2, the issuer determines that its year 1 incurred claims and QIA were in fact $550,000 rather than $500,000. The issuer's 2-year average MLR would equal ($550,000 + $700,000)/($1,000,000 + $1,000,000) = 62.5% and the corresponding rebate would equal (80% − 62.5%) * $1,000,000 = 175,000. Under our proposal, the issuer's preliminary MLR with respect to year 1 as adjusted by the newer incurred claims and QIA data would be calculated as $550,000/$1,000,000 = 55% and the corresponding rebate liability as (80% − 55%) * $1,000,000 = $250,000. The preliminary MLR with respect to year 2 would be calculated as $700,000/$1,000,000 = 70% and the corresponding rebate liability as (80% − 70%) * $1,000,000 = $100,000. The $300,000 rebate initially paid for year 1 would be applied first against the year 1 rebate liability of $250,000, with the remaining $50,000 applied against the year 2 rebate liability of $100,000, resulting in a combined outstanding rebate liability of $250,000 + $100,000 − $300,000 = $50,000. Because the combined outstanding rebate liability is lower than the rebate based on the 2-year average MLR, the rebate payable for year 2 is limited to the lower amount, or $50,000; whereas under the current MLR regulations, the issuer would be required to pay $175,000 in rebates for year 2. In year 3, the rebate based on the 3-year average MLR would be $116,667, while the combined outstanding rebate liability would be zero, resulting in no rebate payable for year 3.

In recognition of the fact that, as discussed above, only a limited subset of issuers may be disadvantaged by the three-year averaging rule and would be able to benefit from this proposal, we propose to make the use of the rebate liability limit optional for issuers. To further facilitate application of this proposal in the least burdensome manner, as well as to address an existing ambiguity regarding applicability of the credibility adjustment, we additionally propose to clarify § 158.232 by defining the term "preliminary MLR" to refer to an MLR calculated without applying any credibility adjustment, and by explicitly specifying instances where § 158.232 is intended to refer to experience of a single year, rather than 3 years. These proposed amendments to § 158.232(d), (e), and (f) will enable issuers that wish to take advantage of the rebate liability limit to rely on the single-year, preliminary MLRs that issuers already calculate as part of determining their credibility adjustment, and minimize the additional reporting associated with calculating the outstanding rebate liability if an issuer elects to exercise the flexibility proposed in § 158.240(d). We seek comments on all aspects of this proposal.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget for review and approval. This proposed rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 16. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this proposed rule that contain ICRs. We generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.[60]

A. ICRs Regarding Upload of Risk Adjustment Data (§ 153.610)

Under the HHS-operated risk adjustment program, HHS uses a distributed data collection approach for enrollee-level enrollment, claims and encounter data that reside on an issuer's dedicated data environment. Under § 153.710(a), an issuer of a risk adjustment covered plan in a State where HHS is operating the risk adjustment or reinsurance program on behalf of the State, as applicable, must provide HHS, through the dedicated data environment, access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data, as specified by HHS. Under § 153.610(a), HHS is proposing that an issuer must submit or make accessible all required risk adjustment data for its risk adjustment covered plans in accordance with the risk adjustment data collection approach established by the State, or by HHS on behalf of the State, including any data that is "protected health information" as that term is defined at 45 CFR 160.103 for purposes of recalibrating the HHS risk adjustment model, in the form and manner specified by HHS. This proposal entails HHS sending a command to all issuers' EDGE servers that issuers must execute, which would provide HHS a dataset that does not identify the EDGE server, plan, issuer, geographic rating area, State, or enrollee, for purposes of obtaining enrollee-level data upon which we can recalibrate the HHS risk adjustment models. Because this EDGE report requires no new data elements and only requires an issuer to execute the command, we do not believe this provision imposes additional burden on issuers of risk adjustment covered plans described under the information collection currently approved under OMB Control Number 0938–1155.

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[60] See May 2015 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates at *http://www.bls.gov/oes/current/oes_stru.htm.*

B. ICRs Regarding Data Validation Requirements When HHS Operates Risk Adjustment (§ 153.630)

Under § 153.630(b), an issuer that offers at least one risk adjustment covered plan in a State where HHS is operating risk adjustment on behalf of the State for the applicable benefit year must have an initial validation audit performed on its risk adjustment data. The cost associated with this requirement is the issuer's time and effort to provide HHS with source claims, records, and enrollment information to validate enrollee demographic information for initial and second validation audits and the issuer's cost to employ an independent auditor to perform the initial validation audit on a statistically valid sample of enrollees. We estimate that each issuer sample will consist of approximately 200 enrollees, and we anticipate that this audit will affect approximately 825 issuers. Beginning with 2018 risk adjustment data validation, HHS proposes to require the review of paid pharmacy claims for all sample enrollees in the initial validation audit. Based on 2015 EDGE reinsurance data, we believe approximately half of all enrollees have pharmacy claims, and of those that do, we would expect approximately six pharmacy claims per enrollee. Therefore, we expect that it would require 30 minutes for an auditor (at a labor cost of $72 per hour) and cost approximately $36 per enrollee to validate paid pharmacy claims. We assume that an initial validation audit would be performed on 165,000 enrollees, with half of them, or 82,500 enrollees, having pharmacy claims. Based on the information above, we estimate that the total additional burden per issuer for initial validation auditors to review and validate paid pharmacy claims would be 50 hours and cost approximately $3,600. Therefore, for 825 issuers, the total annual burden of conducting initial validation audits would be 41,250 hours with an equivalent cost of approximately $2.97 million. We will revise the information collection currently approved under OMB Control Number 0938–1155 with an October 31, 2017 expiration date to account for this additional burden.

C. ICR Regarding the Interim and Final Discrepancy Reporting Processes for Risk Adjustment Data Validation When HHS Operates Risk Adjustment (§ 153.630(d))

Under § 153.630(d)(1), we propose that in the manner set forth by HHS, an issuer must confirm the sample or file a discrepancy report within 15 calendar days to dispute the HHS risk adjustment data validation sample set forth by HHS in the HHS–RADV Final Reports. In § 153.630(d)(2), we propose that in the manner set forth by HHS, an issuer may file a discrepancy report within 30 calendar days to dispute the findings of a second validation audit or the calculation of a risk score error rate.

We estimate that 825 issuers of risk adjustment covered plans would be subject to this requirement, and that issuers would review the HHS-risk adjustment data validation final reports, specifically the initial validation audit sample set for the interim discrepancy reporting process. For the final discrepancy reporting process, set forth in proposed § 153.630(d)(2), issuers would review the results of the second validation audit and the calculation of a risk score error rate. On average, we estimate that it would take a business operations specialist (at an hourly labor cost of $78) approximately 2 hours to respond to an interim report and 6 hours to respond to the interim and final discrepancy reporting process. The total burden for each issuer would be 8 hours with an equivalent cost of $624. Therefore, we estimate an aggregate annual burden of 6,600 hours with an equivalent cost of $514,800 for 825 issuers as a result of these requirements. We will revise the information collection currently approved under OMB Control Number 0938–1155 with an October 31, 2017 expiration date to account for this additional burden.

D. ICR Regarding Standardized Options in SBE–FPs (§ 155.20)

In proposed § 155.20, we propose that an SBE–FP must notify HHS if it wants HHS–designed standardized options to receive differential display, by a date to be specified in guidance. We anticipate that fewer than 10 SBE–FPs would submit this information to HHS annually. Under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it would affect fewer than 10 entities in a 12-month period.

E. ICR Regarding Differential Display of Standardized Options on the Web Sites of Agents and Brokers (§ 155.220) and QHP Issuers (§ 156.265)

We propose to require web-brokers and QHP issuers that utilize the direct enrollment pathway to differentially display standardized options in the 2018 plan year and beyond, consistent with the approach adopted by HHS for display on the Exchange Web site, unless HHS approved a deviation. This policy would require direct enrollment entities to prominently display standardized options in a manner that makes them clear to consumers. We estimate that a total of 160 web-brokers and QHP issuers participate in the FFEs and SBE–FPs and would be required to comply with the standard. We estimate it would take a mid-level software developer (at a rate of $96.82 per hour) approximately 2 hours annually to develop a differential display for standardized options. We estimate an annual cost burden of approximately $193.64 per direct enrollment entity. The total annual burden will be 320 hours with an equivalent cost of approximately $30,982.40.

We anticipate that fewer than 10 web-brokers and issuers would submit a request to deviate from the manner adopted by HHS for display on HealthCare.gov. Under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it would affect fewer than 10 entities in a 12-month period.

F. ICR Regarding Ability of States To Permit Agents and Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

We propose a number of requirements for web-brokers related to the direct enrollment process such as prominently displaying information regarding consumers' eligibility for APTC, allowing consumers to make attestations regarding APTC, and providing for the maintenance of electronic records for purposes of audit. At §§ 156.265 and 156.1230, we propose a number of parallel provisions for issuers using the direct enrollment channel. We would provide additional detail regarding the specific requirements under these rules in guidance in the future. At that time, we would estimate the burden associated with these requirements, solicit public comment, and request OMB approval in accordance with the PRA, as may be necessary.

G. ICR Regarding Eligibility Redeterminations (§ 155.330)

We propose to permit an Exchange to choose among three alternatives when the Exchange identifies updated information regarding compliance with the income tax filing and reconciliation requirement under § 155.305. An Exchange may either follow the process described in paragraph (e)(2)(i), a process specified by the Secretary in guidance, or an alternative process proposed by the Exchange and approved by the Secretary. HHS anticipates that it would require Exchanges requesting approval for an alternative process to submit a brief description of the alternative process, and a justification for how the process satisfies the approval criteria outlined in § 155.330(e)(2)(iii)(C). Given the availability of two alternative processes, we anticipate that fewer than 10 Exchanges would submit a proposal. Therefore, under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it would affect fewer than 10 entities in a 12-month period.

We also propose to permit the Exchange to recalculate APTC using the procedure described in § 155.330(g)(1) or an alternate procedure approved by HHS on a transitional basis. HHS anticipates that it would require participating Exchanges to submit a brief description of the alternate procedure and the extent to which the alternate procedure would protect tax filers from an excess APTC repayment. Here too, we anticipate that fewer than 10 Exchanges would submit a proposal. Under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it would affect fewer than 10 entities in a 12-month period.

H. ICR Regarding Termination of Exchange Enrollment or Coverage (§ 155.430(b)(2)(iii))

We are proposing to amend § 155.430(b)(2)(iii) to clarify that when an issuer seeks termination of a QHP purchased on an Exchange via a rescission under § 147.128, it must first demonstrate, to the reasonable satisfaction of the Exchange, that the basis for the rescission is appropriate, if the Exchange requires such a demonstration. This would require the issuer to provide information related to the termination to the Exchange. We do not anticipate that all Exchanges will subject issuers to this requirement. We anticipate that fewer than 10 issuers would be subject to this requirement annually. Under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it would affect fewer than 10 entities in a 12-month period.

I. ICR Regarding QHP Request for Reconsideration (§ 155.1090)

We propose to add § 155.1090 to create a process for an issuer that has applied to an FFE for certification of QHPs and has been denied certification to request reconsideration. We anticipate that fewer than 10 issuers per year would request reconsideration. Under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it would affect fewer than 10 entities in a 12-month period.

J. ICR Regarding Notification by Issuers Denied Certification (§ 156.290)

In proposed § 156.290 we propose that QHP issuers would be required to provide a notification to enrollees within 30 days of the date of HHS's denial of certification for a subsequent, consecutive certification cycle. We anticipate that fewer than 10 issuers would be subject to this requirement annually. Under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it would affect fewer than 10 entities in a 12-month period.

K. ICR Regarding the Discrepancy Reporting Processes for the Reconciliation of the Cost-sharing Reduction Portion of Advance Payments (§ 156.430(h))

Under § 156.430(h)(1), we proposed that, if an issuer files a discrepancy report to dispute the notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments, it must file the discrepancy report within 30 calendar days of notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments as described in § 156.430(e), in the manner set forth by HHS.

We estimate that of approximately 360 QHP issuers that submit cost-sharing reduction reconciliation data, less than ⅓ would file a discrepancy report to dispute the notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments. Issuers would review the notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments for this discrepancy reporting process. On average, we estimate that it would take a business operations specialist (at an hourly labor cost of $78) approximately 6 hours to review the requirements of the discrepancy reporting process, to determine whether the issuer should submit a discrepancy report, to categorize the discrepancy, and to write a description of the discrepancy for submission to HHS. Additionally, we estimate that it would take a computer programmer (at an hourly labor cost of approximately $78) approximately 12 hours to develop the pipe-delimited file for reporting the discrepancy, based on the technical specifications published by HHS, and to submit the discrepancy file to HHS through the electronic file transfer system. Therefore, we estimate that the total burden for each issuer would be approximately 18 hours with an equivalent cost of $1,404. Therefore, assuming that no more than 120 issuers would submit a discrepancy, we estimate a total aggregate annual burden of approximately 2,160 hours with an equivalent cost of $168,480 for issuers as a result of these requirements. We will revise the information collection currently approved under OMB Control Number 0938–1266 with a December 31, 2017 expiration date to account for this additional burden.

L. ICRs Regarding Administrative Appeals (§ 156.1220)

In 45 CFR 156.1220, we established an administrative appeals process to address any issues or errors for advance payment of the premium tax credit, advance payment and reconciliation of cost-sharing reductions, FFE user fees, and the premium stabilization programs, as well as any assessment of a default risk adjustment charge under § 153.740(b). We propose revising § 156.1220 to also address administrative appeals relating to the risk adjustment data validation process.

Under § 153.630(d), an issuer may appeal the findings of a second validation audit or the calculation of a risk score error rate. We propose to amend § 153.630(d) by clarifying the process by which an issuer can appeal the findings of a second validation audit or the calculation of a risk score error rate. We propose requiring issuers to use the administrative appeals process set forth in § 156.1220.

Under § 156.1220(a), we propose to clarify that an issuer may file a request for reconsideration under this section to contest a processing error by HHS,

HHS's incorrect application of the relevant methodology, or HHS's mathematical error with respect to the findings of a second validation audit or the calculation of a risk score error rate.

While the hours involved in a request for reconsideration might vary, for purposes of this burden estimate we estimate that it would take a business operations specialist 1 hour (at an hourly labor cost of $78) to make the comparison and submit a request for reconsideration to HHS. We estimate that 9 issuers, representing approximately 1 percent of issuers of risk adjustment covered plans, subject to risk adjustment data validation, would submit a request for reconsideration, resulting in a total aggregate annual burden of 9 hours with an equivalent cost of approximately $702.

M. ICR Regarding Medical Loss Ratio (§ 158.240)

We are proposing to amend § 158.240 to allow issuers the option of limiting the total rebate payable over the course of a 3-year period with respect to a given calendar year. We anticipate that implementing this proposal would require minor changes to the MLR annual reporting form and we may revise the information collection currently approved under OMB Control Number 0938–1164 to reflect the proposed policy. However, only a small number of issuers would elect the option of additional reporting and we do not expect that the proposed policy would increase the burden.

TABLE 16—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN

Regulation Section	OMB Control No.	Number of respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 153.630 Risk Adjustment Data Validation	0938–1155	825	82,500	0.5	41,250	72	2,970,000	2,970,000
§ 153.630(d) Discrepancy Reporting Processes for Risk Adjustment Data Validation	0938–1155	825	1650	4	6,600	78	514,800	514,800
§§ 155.220, 156.265 Differential Display of Standardized Options ...	NEW	160	160	2	320	96.82	30,982	30,982
§ 156.430(h) Discrepancy Reporting for cost-sharing reduction reconciliation	0938–1266	120	1	18	2,160	78	168,480	168,480
§ 156.1220 Administrative Appeals	NEW	9	9	1	9	68	702	702
Total	....	1,114	84,320	25.5	50,339	392.82	3,684,964	3,684,964

Note: There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 16.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This rule proposes standards related to the risk adjustment program for the 2017 and 2018 benefit years, as well as certain modifications to the program that will protect against the potential effects of adverse selection. The Premium Stabilization Rule and previous Payment Notices provided detail on the implementation of this program, including the specific parameters for the 2014, 2015, 2016, and 2017 benefit years applicable to this program. This rule proposes additional standards related to enrollment and eligibility, consumer assistance tools and programs of an Exchange, web-brokers, cost-sharing parameters, qualified health plans, network adequacy, stand-alone dental plans, guaranteed renewability, the rate review program, the medical loss ratio program, the Small Business Health Options Program, and FFE user fees. These proposed standards represent incremental amendments that are intended to continue to strengthen the Exchanges, improve the stability of the market, and enhance the choices available to consumers, while supporting consumers' ability to make informed choices when purchasing health insurance.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year).

OMB has determined that this proposed rule is "economically significant" within the meaning of section 3(f)(1) of Executive Order 12866, because it is likely to have an annual effect of $100 million in any 1 year. Accordingly, we have prepared an RIA that presents the costs and benefits of this proposed rule.

Although it is difficult to discuss the wide-ranging effects of these provisions in isolation, the overarching goal of the premium stabilization, market standards, and Exchange-related provisions and policies in the Affordable Care Act is to make affordable health insurance available to individuals who do not have access to affordable employer-sponsored coverage. The provisions within this proposed rule are integral to the goal of expanding coverage. For example, the risk adjustment program helps prevent risk selection and decrease the risk of financial loss that health insurance issuers might otherwise expect in 2018 and Exchange financial assistance helps low- and moderate-income consumers and American Indians/Alaska Natives purchase health insurance. The combined impacts of these provisions affect the private sector, issuers, and consumers, through increased access to health care services, decreased uncompensated care, lower premiums, and increased plan transparency. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these provisions are expected to increase access to affordable health coverage.

HHS anticipates that the provisions of this proposed rule will help further HHS's goal of ensuring that all consumers have access to quality, affordable health care and are able to make informed choices, that Exchanges operate smoothly, that the risk adjustment program works as intended, and that SHOPs are provided flexibility. Affected entities such as QHP issuers would incur costs to comply with the proposed provisions. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A–4, Table 17 depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action.

This proposed rule implements standards for programs that will have a number of effects, including providing consumers with affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify certain benefits of this proposed rule—such as improved health outcomes and longevity due to continuous quality improvement, and increased insurance enrollment—and certain costs—such as the cost of providing additional medical services to newly-enrolled individuals. The effects in Table 17 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this proposed rule. The annualized monetized costs described in Table 17 reflect direct administrative costs to health insurance issuers and web-brokers as a result of the proposed provisions, and include administrative costs related to requirements that are estimated in the Collection of Information section of this proposed rule. The annual monetized transfers described in Table 17 include costs associated with the risk adjustment user fee paid to HHS by issuers, and a decrease in MLR rebates to consumers. For 2018, we are proposing to collect a total of $35 million in risk adjustment user fees or $1.32 per enrollee per year from risk adjustment issuers, an increase from $24 million in benefit year 2017 when we established a $1.56 per-enrollee-per-year risk adjustment user fee amount. As in 2017, the risk adjustment user fee contract costs for 2018 include costs for risk adjustment data validation; however, we expect increased enrollment in 2018 HHS risk adjustment covered plans, which decreases the per enrollee amount.

The annual monetized transfers described in Table 17 include a decrease in MLR rebates to consumers.

TABLE 17—ACCOUNTING TABLE

Benefits:
Qualitative:

- Increased enrollment in the individual market leading to improved access to health care for the previously uninsured, especially individuals with medical conditions, which will result in improved health and protection from the risk of catastrophic medical expenditures.
- Improved transparency and shopping experience for consumers due to new, updated standardized options and their differential display; and protections relating to direct enrollment.
- Provide adequate time to newly qualified employees to make informed decisions regarding their coverage in the SHOP.
- Ensure plan choice, allowing individuals to find coverage that fit their needs.

Costs:	Estimate (million)	Year dollar	Discount rate	Period covered
Annualized Monetized ($/year)	$3.68 3.68	2016 2016	7 3	2017–2021 2017–2021

Costs reflect administrative costs incurred by issuers and web-brokers to comply with provisions in this final rule.

Transfers:	Estimate (million)	Year dollar	Discount rate	Period covered
Annualized Monetized ($/year)	$22.2 22.6	2016 2016	7 3	2017–2021 2017–2021

- Transfers include risk adjustment user fees for 2018–2021 (assuming that they remain the same during this time period), which are transfers from health insurance issuers to the Federal government; and a reduction in total rebate payments by issuers which is a transfer from enrollees to shareholders or nonprofit stakeholders in individual, small and large group markets, resulting from adjustment in MLR methodology.

Qualitative:

- More accurate risk adjustment charges and payments due to change in risk adjustment methodology.

This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office's (CBO) analysis of the Affordable Care Act's impact on Federal spending, revenue collection, and insurance enrollment. The temporary risk corridors program and the transitional reinsurance program end after the benefit year 2016. Therefore, the costs associated with those programs are not included in Tables 17 or 18 for fiscal years 2019–2021. Table 18 summarizes the effects of the risk adjustment program on the Federal budget from fiscal years 2017 through 2021, with the additional, societal effects of this proposed rule discussed in this RIA. We do not expect the provisions of this proposed rule to significantly alter CBO's estimates of the budget impact of the premium stabilization programs that are described in Table 18. We note that transfers associated with the risk adjustment and reinsurance programs were previously estimated in the Premium Stabilization Rule; therefore, to avoid double-counting, we do not include them in the accounting statement for this proposed rule (Table 18).

TABLE 18—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT, REINSURANCE, AND RISK CORRIDORS PROGRAMS FROM FISCAL YEAR 2017–2021

[In billions of dollars]

Year	2017	2018	2019	2020	2021	2017–2021
Risk Adjustment, Reinsurance, and Risk Corridors Program Payments	10	8	8	9	9	44
Risk Adjustment, Reinsurance, and Risk Corridors Program Collections *	11	7	8	9	9	44

Note 1: Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time.

Note 2: The CBO score reflects an additional $2 million in collections in FY 2015 that are outlaid in the FY 2016–FY 2020 timeframe. CBO does not expect a shortfall in these programs.

Source: Congressional Budget Office. Federal Subsidies for Health Insurance Coverage for People Under Age 65: Tables From CBO's March 2016 Baseline *https://www.cbo.gov/sites/default/files/51298-2016-03-HealthInsurance.pdf.*

1. Fair Health Insurance Premiums

The proposed regulations would amend § 147.102(d) to create multiple child age bands rather than a single age band for all individuals aged 0 through 20. Establishing single-year age bands starting at age 15 is likely to result in small annual increases in premiums for children age 15 to 20, which would help mitigate large premium increases attributable to age due to the transition from child to adult age rating.

2. Guaranteed Renewability

This proposed rule would specify the circumstances in which the discontinuation of all coverage currently offered by an issuer in a market in a State would not be considered a market withdrawal subject to the 5-year ban on market re-entry. We believe this proposal is generally consistent with State regulation of health insurance and therefore would not have a material impact on issuers or enrollees. These changes would benefit consumers since imposing the 5-year ban on market re-entry in these situations could result in disruption for consumers and reduced competition in some markets.

3. Risk Adjustment

The risk adjustment program is a program created by the Affordable Care Act in which States, or HHS on behalf of States, collects charges from health insurance issuers that attract lower-risk populations in order to use those funds to provide payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, thereby reducing incentives for issuers to avoid higher-risk enrollees. We established standards for the administration of the risk adjustment program, in subparts D and G of part 45 of the CFR. The proposed modifications to the risk adjustment model aims to improve the methodology and would result in more accurate risk adjustment charges and payments and mitigate any residual incentive for risk selection.

A State approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. As described in the 2014, 2015, 2016 and 2017 Payment Notices, if HHS operates risk adjustment on behalf of a State, it will fund its risk adjustment program operations by assessing a risk adjustment user fee on issuers of risk adjustment covered plans. For the 2018 benefit year, we estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for 2018 will be approximately $35 million, and that the risk adjustment user fee would be approximately $1.32 per enrollee per year. The risk adjustment user fee contract costs for 2018 include costs related to 2018 risk adjustment data validation, and are higher than the 2017 contract costs as the result of some contracts that were rebid.

4. SHOP

The SHOPs facilitate the enrollment of eligible employees of eligible small employers into small group market health insurance plans. A qualitative analysis of the costs and benefits of establishing a SHOP was included in the RIA published in conjunction with the Exchange Establishment Rule.[61]

In § 155.230(d)(2), we propose requiring SHOPs to make electronic notices the default method of sending SHOP notices to employers and employees, unless otherwise required by State or Federal law. Electronic notices would provide a more cost effective way for SHOPs to distribute required notices and should decrease the SHOP's costs for notifications.

In § 155.725(g), we propose changes to the enrollment process for newly qualified employees. We believe the proposed amendments would provide newly qualified employees with adequate time to make informed decisions regarding their coverage and are likely to have a negligible impact on plan premiums and would ensure that employers do not exceed the waiting period limits under § 147.116.

5. Direct Enrollment—Standardized Options Differential Display and Privacy/Security and Oversight

We did not require QHP issuers or web-brokers to adhere to differential display requirements of standardized options when using a non-Exchange Web site to facilitate enrollment in a QHP through an Exchange for the 2017 plan year, but we noted that we would consider whether to propose such a standard in the future. We now propose to amend § 155.220(c)(3)(i) by adding new paragraph (c)(3)(i)(H) to require web-brokers to differentially display standardized options consistent with the approach adopted by HHS, unless a deviation is approved by HHS and to amend § 156.265(b)(3) by adding new paragraph (b)(3)(iv) to likewise require QHP issuers that conduct direct enrollment to differentially display standardized options in such manner approved by HHS. Requiring web-brokers and QHP issuers using the direct enrollment pathway to make changes to their respective QHP display systems may result a slight increase in administrative costs but would help further our goal of ensuring that all consumers have access to quality and affordable health care and are able to make informed choices.

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[61] Available at *http://cciio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf.*

In §§ 155.220, 156.265, and 156.1230, we propose requirements for web-brokers and issuers related to the direct enrollment process that would provide consumer protections and ensure that consumers have necessary information to select coverage that would best fit their needs. Web-brokers and issuers would incur administrative costs to comply with these requirements.

6. Eligibility and Enrollment Provisions

In § 155.400, we propose to provide Exchanges with the discretion to allow issuers experiencing billing or enrollment problems due to high volume or technical errors to implement a reasonable extension of the binder payment deadlines in § 155.400(e)(1). This proposal aims to retain consumers on the Exchange and to mitigate the problems associated with issuers receiving high-volumes of enrollments in a short timeframe. There would be no added cost to issuers who choose to implement the optional binder payment extensions, while ensuring that they would not lose enrollees who have not paid their binder payments simply because they did not receive their bills due to a processing backlog or a technical error. Consumers would benefit by having a reasonable amount of time to pay their binder payments, which should prevent coverage cancellations due to enrollment irregularities which are not the fault of the consumer.

In § 155.420, we propose to codify several special enrollment periods that are already provided through the Exchange. By codifying these, we seek to ensure that these existing special enrollment periods are applied consistently across Exchanges, and to provide both issuers and consumers with greater certainty in how these special enrollment periods are applied. We believe that this certainty would contribute to greater stability in the market, and in the use of these special enrollment periods, specifically.

We propose to amend § 155.430(b)(2)(iii) to require that when an issuer seeks termination of a QHP on an Exchange via a rescission for fraud or misrepresentation of material fact under § 147.128, it must first demonstrate, to the reasonable satisfaction of the Exchange, that the basis for the rescission is appropriate, if the Exchange requires such a demonstration. This would not restrict issuers' ability to rescind coverage when an individual or a party working on behalf of an individual fraudulently enrolls in coverage, while protecting consumers whose verification and enrollment conform to FFE and SBE–FP rules and guidance.

7. Standardized Options

We are proposing new standardized options for 2018, which are updated versions of the ones finalized in the 2017 Payment Notice. As in 2017, offering standardized options will be voluntary for QHP issuers in 2018. In keeping with the methodology used to design standardized options in 2017, we designed the proposed 2018 standardized plans based on the median cost-sharing features of the most popular 2016 QHPs, based on enrollment to ensure minimal market disruption and impact on premiums. For 2018, we are proposing additional standardized options at each metal level and plan variation with the goal of having at least one option at each metal level that would comply with every State's respective cost-sharing laws as applicable. Each applicable State would have one standardized option at each metal level and plan variation that issuers would then be able to choose to offer. In the 2017 Payment Notice, we attempted to estimate the potential impact that the introduction of standardized options would have on premiums established by QHPs. As we previously estimated, we do not anticipate that standardized options would impact 2018 plan premiums significantly. Rather, the proposed options would allow each applicable State to have a set of standardized options that most closely reflects QHPs in the State while meeting any State cost-sharing mandates. This policy should continue to improve simplicity and transparency for consumers during the shopping experience. To the extent it facilitates consumer shopping, it could put modest downward pressure on premiums.

8. User Fees

To support the operation of FFEs, we require in § 156.50(c) that a participating issuer offering a plan through an FFE must remit a user fee to HHS each month equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE. In this proposed rule, for the 2018 benefit year, we propose a monthly FFE user fee rate equal to 3.5 percent and, for a State-based Exchange that relies on the Federal platform, 3.0 percent of the monthly premium. We had estimated the user fee transfers in the 2017 Payment Notice and there are no additional incremental charges. To avoid double-counting, we do not include the user fee costs in the accounting statement for this rule (Table 17). For the user fee charges assessed on issuers in the FFE and State-based Exchanges using the Federal platform, we intend to seek an exception to OMB Circular No. A–25R, which requires that the user fee charge be sufficient to recover the full cost to the Federal government of providing the special benefit. We seek this exception to ensure that the FFE can support many of the goals of the Affordable Care Act, including improving the health of the population, reducing health care costs, and providing access to health coverage as advanced by § 156.50(d).

9. Levels of Coverage

At § 156.140, we propose to change the de minimis range of bronze plans under certain circumstances. We believe that this policy would not be disruptive to the current bronze plan market as it would allow more bronze plans the flexibility in creating plan designs within the increased de minimis range, as well as allow more options for issuers to leave 2017 cost-sharing structures unchanged. We also believe this policy would allow issuers to continue to offer a range of bronze plans as the AV Calculator is updated in future years, which is good for consumers. Plans are not required to utilize this proposed option, and we do not anticipate any significant impact on average bronze plan premiums from this proposed policy.

10. Provisions Related to Cost Sharing

The Affordable Care Act provides for the reduction or elimination of cost sharing for certain eligible individuals enrolled in QHPs offered through the Exchanges. This assistance will help many low- and moderate-income individuals and families obtain health insurance—for many people, cost sharing is a barrier to obtaining needed health care.[62]

We set forth in this proposed rule the reductions in the maximum annual limitation on cost sharing for silver plan variations. Consistent with our analysis in previous Payment Notices, we developed three model silver level QHPs and analyzed the impact on their AVs of the reductions described in the Affordable Care Act to the estimated 2018 maximum annual limitation on cost sharing for self only coverage $7,350. We do not believe these changes would result in a significant economic impact. Therefore, we do not believe the provisions related to cost-sharing reductions in this proposed rule would have an impact on the program established by and described in the 2015, 2016, and 2017 Payment Notices.

We also proposed the premium adjustment percentage for the 2018 benefit year. Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. The annual premium adjustment percentage sets the rate of increase for three parameters detailed in the Affordable Care Act: The annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code, and the assessable payments under sections 4980H(a) and 4980H(b). We believe that the proposed 2018 premium adjustment percentage of 16.17303196 percent is well within the parameters used in the modeling of the Affordable Care Act, and we do not expect that these proposed provisions would alter CBO's March 2015 baseline estimates of the budget impact.

11. Qualified Health Plan Minimum Standards

In § 156.200(c), we propose to specify that, to satisfy the requirements in these sections, QHPs must be offered through the applicable Exchange at both the silver and gold coverage levels throughout each service area in which the issuer applying for certification offers coverage through the Exchange. Since most issuers are already following these requirements, it is unlikely that there would be any impact on premiums, while ensuring continued plan choice for consumers.

In the 2017 Payment Notice, we finalized a network breadth policy through which we would categorize networks based on their relative size, in addition to other policies. We seek comment regarding how this should apply to "integrated plans," such as staff model HMOs. We expect the policy would continue to improve transparency for consumers and the shopping experience.

Proposed § 156.272 would establish as a condition of certification that QHP issuers must make their QHPs available for enrollment through the Exchanges for the duration of the timeframe for which the plan was certified, unless a basis for suppression under § 156.815 applies. QHP issuers in FFEs and FF–SHOPs that do not comply with this requirement could be subject to CMPs or a two-year ban. This would raise costs or burdens on issuers, who could be forced to remain on the Exchange or face a 2-year ban or CMPs in certain situations. However, we do not believe that violations of the proposed requirement of full year participation under § 156.272 are happening on a wide scale, which minimizes any potential impact.

12. Medical Loss Ratio

In this proposed rule, we propose to amend § 158.121 to align with the requirement that, beginning in 2014, issuers must offer non-grandfathered coverage for a consecutive 12-month period and enable more issuers to defer reporting of the experience of new business in the MLR calculation. In general, deferring reporting of new business effectively enables new and rapidly growing issuers to use a 4-year, rather than a 3-year average MLR. This in turn increases the likelihood that low MLRs in the initial years will be offset by higher MLRs in later years and that only a portion of the rebates generated by the experience of initial years will ultimately be paid. Deferring reporting of new business also eliminates the rebate payment following the first year and instead spreads it over the following 3 years (that is, includes the rebate attributable to year 1 with rebates payable for years 2 through 4). Based on data from the 2013 and 2014 MLR reporting years, we estimate that allowing issuers to defer experience of newly sold policies with full 12 months of experience when 50 percent or more of an issuer's earned premium comes from such policies could reduce total rebate payments from issuers to consumers over a 4-year period by up to a total of $11.6 million.

We additionally propose to amend § 158.240 to allow issuers the option of limiting the total rebate payable over the course of a 3-year period with respect to a given calendar year, as well as to clarify references to single-year and preliminary MLRs in § 158.232. We estimate no impact from the proposed clarifications to § 158.232 because these clarifications are intended to simplify reporting for purposes of calculating the rebate limit proposed in § 158.240 and do not change the manner in which issuers currently calculate the credibility adjustment. Because the proposed amendments to § 158.240 generally would only impact new and rapidly growing established issuers whose MLRs initially fall below the standard and increase in subsequent years, the magnitude of the impact of the proposed limit on the rebate liability would depend on how issuers' enrollment and MLRs change in 2015 and later. Because the majority of new issuers have expanded or intend to expand into new markets in 2014 or later, the 2014 and earlier MLR reports, which are the only data source available at this time, are an insufficient source of data on the types of issuers that would be impacted by this proposal. In addition, significant reporting differences exist between 2011–13 and 2014 and later MLR data, and some rebates that were paid for 2014 are likely to be outliers and may therefore exaggerate estimates. Consequently, while we expect the proposal to decrease the amount of rebates paid by new and rapidly growing issuers to consumers, we are not able to estimate the magnitude of the decrease with a high degree of certainty.

D. Regulatory Alternatives Considered

In developing the policies contained in this proposed rule, we considered numerous alternatives to the presented proposals. Below we discuss the key regulatory alternatives that we considered.

For the proposals in parts 146, 147 and 148, we considered not changing our interpretation of what constitutes a market withdrawal when an issuer transfers all of its products to a related issuer or replaces all of its products with new products with changes that exceed the scope of a uniform modification of coverage. However, this approach could result in fewer product offerings, as issuers would be obligated to leave the market due to the 5-year prohibition on issuing coverage after discontinuing all coverage in a market. This approach could also unnecessarily restrict issuer corporate structuring transactions, reduce market competition and consumer choice, and conflict with States' approaches.

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[62] Brook, Robert H., John E. Ware, William H. Rogers, Emmett B. Keeler, Allyson Ross Davies, Cathy D. Sherbourne, George A. Goldberg, Kathleen N. Lohr, Patricia Camp and Joseph P. Newhouse. *The Effect of Coinsurance on the Health of Adults: Results from the RAND Health Insurance Experiment.* Santa Monica, CA: RAND Corporation, 1984. Available at: *http://www.rand.org/pubs/reports/R3055.*

For the proposals in part 147, we considered not changing the uniform child age band. This approach would have maintained the use of a single age band for rating purposes for all individuals age 0 through 20. We determined that creating multiple child age bands more accurately reflects the health risk of children and minimizes the increase in premium attributable to age when an individual attains age 21.

For the proposals in part 153, we considered various approaches to addressing partial year enrollment in the risk adjustment model, including separate models by enrollment duration, and interaction factors of enrollment duration combined with high- and medium-cost conditions. However, based on commenter feedback to the March 31, 2016 White Paper and our analysis of MarketScan® data, HHS determined that the enrollment duration additive factors are preferred and will best address partial year enrollees in the short term.

We considered four different hybrid models for the inclusion of prescription drugs in the HHS risk adjustment methodology: An imputation only model, a prescription drug-dominant model, a flexible model, and a severity only model. Commenters to the White Paper suggested that we use the imputation only model or the flexible model, with constraints to prevent an issuer from being compensated less for recording prescription drug utilization for an enrollee. We have imposed constraints on the flexible model so that the coefficients for the drug terms are greater than zero, preventing such a situation. We are adding two severity-only drug-diagnosis pairs on top of ten imputation/severity drug-diagnosis pairs.

We considered a threshold of $1 million and a coinsurance rate of 80 percent for the proposed high-cost enrollee pool in the risk adjustment proposal, which was supported by commenters to the White Paper. However, many more commenters suggested that the high-cost enrollee pool could be subject to gaming among issuers and would not incentivize cost containment efforts. Therefore, we are proposing a higher threshold of $2 million and a 60 percent coinsurance rate for the high-cost enrollee pool in the risk adjustment model. We also considered a PMPM adjustment to the transfer formula for this high-cost enrollee pool, but we are proposing a percent of per member per month premium adjustment to the transfer formula, to better align with the transfer formula's adjustment at the billable member month premiums.

We considered using only 2014 MarketScan® data for 2018 recalibration. However, commenters to the White Paper preferred to continue using the three-year blended approach. Commenters also supported issuing final coefficients in guidance, which we have proposed to do and are seeking comment on the timing of those final coefficients.

We considered alternative methodologies to recalibrating the 2019 risk adjustment model using EDGE summary level data instead of enrollee level data, as was proposed by one commenter to the White Paper. However, using EDGE summary level data would not enhance the existing risk adjustment models, as the model specifications would need to be known to create the models, and thus would prevent exploratory research and other types of analyses required for research, development and refinement of the risk adjustment models for their continuous improvement. Further, if summary level data were used, quality checks could not be performed on the input data, and additional improvements to address partial year enrollment could not be explored.

For the proposals regarding standardized options, we considered taking no action in designing additional plans per metal level to account for State cost-sharing laws. However, without this proposed change, issuers in States with conflicting cost-sharing laws would not be able to offer standardized options. We believe that it is important for issuers in each State in which an FFE or SBE–FP operates to have the choice to offer standardized options. We also considered designing a set of standardized plans for each State. However, HHS currently lacks the resources to propose this option.

For the proposal at § 155.205(c)(2)(iii), we considered requiring QHP issuers and web-brokers subject to the rule to look only to the LEP populations in the State where the entity is registered or licensed, such as through an issuer's Health Insurance Oversight System (HIOS) ID, when identifying the languages in which taglines must be provided under the rule. However, we believe that using such a definition would not recognize that many insurance companies use a common technology platform for their issuers across multiple States, and would pose difficult operational challenges for many such entities without significantly improving access.

For the proposal at §§ 155.220 and 156.265, we considered not requiring differential display of standardized options by web-brokers or QHP issuers. However, this would have made it less likely that consumers using a non-Exchange Web site would be aware of the standardized options available. We believe that the requirement for differential display of standardized options will help consumers using non-Exchange Web sites more easily compare and choose amongst the available plans. We note that we would not require the manner of differentiation to be identical to the one adopted for displaying standardized options on *HealthCare.gov*, and issuers are not required to offer, and consumers are not required to purchase, standardized options.

For proposals at § 155.400, we considered alternatives to our proposal to allow issuers the option to extend binder payment deadlines when issuers experience volume-related backlogs or technical errors that make it difficult for enrollees to pay their binder payments on time. For example, we considered relying on ad hoc solutions, such as extensions or remedies resembling reinstatements, when problems arise. We believed, however, that codifying the proposed optional extensions will give issuers and consumers alike more certainty and provide for better remedies when consumers experience difficulties during the enrollment process.

For the proposals at § 155.420, we considered not codifying the existing special enrollment periods for consumers who are or were a victim of domestic abuse or spousal abandonment and need to enroll in coverage apart from his or her abuser or abandoner, have been determined ineligible for Medicaid or CHIP, have been impacted by a material plan or benefit display error, or have resolved a citizenship or immigration inconsistency post-expiration, all currently provided through guidance. We also considered not standardizing the availability of the special enrollment period for Indians to non-Indian dependents enrolling at the same time as the Indian. However, we believe that codifying these special enrollment periods provides needed permanence and clarity for these special enrollment periods. This is important to ensure that they continue to be available, are equitably applied across Exchanges, and that consumers, assisters, issuers, and other stakeholders have a common understanding of the parameters and coverage effective dates associated with each of these special enrollment periods. In this rule, we seek to ensure transparency, stability, and appropriate utilization of special enrollment periods by codifying certain special enrollment periods that we have made available in prior guidance. After weighing our options, we determined that codifying these currently available special enrollment periods is in the best interest of consumers and other Exchange stakeholders.

We considered alternatives to amending § 155.430 in order to protect consumers from having their coverage rescinded for reasons the FFE does not consider reasonable, such as rescissions based on allegations of fraud, despite the disputed information having been verified by the FFE during the enrollment process. One alternative was to issue guidance that would explain to issuers that rescissions based on claims of fraud arising from information provided to and verified by the FFE would not be permissible. Another alternative considered was to work with issuers to prevent rescissions considered unreasonable by the FFE, but to decline to pursue rulemaking. After considering all options, we chose to amend § 155.430(b)(2)(iii) in order to provide more consumer protection.

For the proposals related to SHOPs, we considered maintaining several provisions for the SHOPs. Specifically, we considered maintaining the current requirements at § 155.725(g)(1) and (2), which provide that an employee who becomes a qualified employee outside of the initial or annual open enrollment period must have an enrollment period beginning on the first day of becoming a qualified employee, and require the effective date of coverage to generally be determined in accordance with § 155.725(h). Similarly, we considered maintaining the current requirements at § 155.230(d)(2), which require paper notices to be the default option for SHOPs, so that employers and employees must opt into electronic notices. Finally, we considered maintaining existing requirements in State-based Exchanges using the Federal platform for SHOP eligibility, enrollment, or premium aggregation functions. However, we decided to propose the policies in this proposed rule in order to ensure that employers do not exceed the waiting period limits under § 147.116, to provide SHOPs with more cost-effective alternatives to sending notices, to ensure efficient SHOP operations, and to minimize the potential customization costs that could be associated with permitting State-based Exchanges to use the Federal platform for SHOP functions.

We considered alternative proposals for increasing the de minimis range for bronze plans. We considered simply increasing the de minimis range for bronze plans to extend above 62 percentage points without requiring that plans include certain plan design features in order to qualify for the extended de minimis range. This option could give issuers, and as a result consumers, more flexibility and choice with regards to bronze plan designs. However, we believe that the proposed policy better ensures that bronze plans are not less generous than catastrophic plans.

For the proposals at § 156.200(c)(1), we propose to specify that, to satisfy the requirements in that section, QHPs must be offered through an Exchange at both the silver and gold coverage levels throughout each service area in which the issuer offers coverage through the Exchange. We could have opted not to specify this in regulation; however, issuers could have misinterpreted the policy and not offered a silver and gold plan in the applicable service areas. This could result in fewer silver and gold plans available for consumers to select, and thus less choice for consumers. It also could complicate the calculation of the APTC for an individual market consumer. By revising our regulation, we ensure that consumers have an adequate choice of QHPs at different coverage levels to select from and that we are able to calculate APTC for all eligible individual market consumers.

For the proposals at § 156.272 to require issuer participation for the entirety of the period for which the plan was certified, we considered taking no action. However, we are concerned that inaction could result in limited access for qualified individuals and qualified employees outside of open enrollment periods.

For the proposed changes to § 156.290, we considered not making any changes. However, that could have led to enrollees in plans that are not certified for a subsequent, consecutive certification cycle not knowing as soon as possible that they may have to choose another plan during the annual open enrollment period.

For the proposals in part 158, we considered an alternative proposal for addressing the impact of MLR and rebate calculation on new and rapidly growing issuers. Specifically, we considered allowing new and rapidly growing issuers to include in the MLR calculation rebates they paid within the first 2 years of entering or expanding in a State market, which would be similar to how the 3-year average calculation was phased in for all issuers when the MLR requirements were first implemented. However, in contrast to the initial years of implementation of the MLR requirements, when all issuers had to calculate their first two MLRs using only 1 or 2 years of data, presently, as described in more detail in the preamble to this proposed rule, only a small subset of issuers are affected by the 3-year averaging in a manner that merits an adjustment. We note that inclusion of rebates paid for prior years in the MLR calculation for the current year is generally not appropriate for established and certain new issuers, as it would distort the 3-year average and effectively lower the MLR standards required by section 2718 of the PHS Act. Therefore, the prior year rebate approach would need to be limited to only the new and growing issuers that are adversely affected by the 3-year averaging. In practice, it would be extremely challenging to define enrollment or premium levels, growth rates, and patterns in year-over-year changes in MLRs that would appropriately distinguish new and growing issuers that are disadvantaged by the 3-year averaging from issuers that merely experience ordinary enrollment fluctuations or otherwise would gain an unfair advantage by being able to include prior year rebates in their MLR calculation. Because the proposed approach of limiting the total rebate liability payable with respect to a given calendar year is designed to only benefit new and rapidly growing issuers who are negatively impacted by the 3-year averaging, we believe that the proposed approach is a more effective and objective way to reduce barriers to entry and promote competition in health insurance markets while at the same time preserving the protections promised to consumers by the law.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a "small entity" as: (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a not-for-profit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of "small entity." HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this proposed rule, we propose standards for the risk adjustment program, which are intended to stabilize premiums as insurance market reforms are implemented and Exchanges facilitate increased enrollment. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for "small entities" established by the SBA, we do not believe that an initial regulatory flexibility analysis is required for such firms.

For purposes of the RFA, we expect the following types of entities to be affected by this proposed rule:

- Health insurance issuers.
- Group health plans.

We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $38.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $32.5 million or less.

Based on data from MLR annual report submissions for the 2014 MLR reporting year, approximately 118 out of 525 issuers of health insurance coverage nationwide had total premium revenue of $38.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since almost 80 percent of these small companies belong to larger holding groups, and many if not all of these small companies are likely to have non-health lines of business that would result in their revenues exceeding $38.5 million. Only nine of these 118 potentially small entities, all of them part of larger holding groups, are estimated to experience a decrease in the rebate amount under the proposed amendments to the MLR provisions of this proposed rule in part 158. Therefore, we do not expect the proposed provisions of this rule regarding MLR to affect a substantial number of small entities.

In this proposed rule, we proposed standards for employers that choose to participate in a SHOP Exchange. The SHOPs generally are limited by statute to employers with at least one but not more than 50 employees, unless a State opts to provide that employers with 1 to 100 employees are "small employers." For this reason, we expect that many employers who would be affected by the proposals would meet the SBA standard for small entities. We do not believe that the proposals impose requirements on employers offering health insurance through a SHOP that are more restrictive than the current requirements on small businesses offering employer sponsored insurance. We believe the processes that we have established for SHOP eligibility and enrollment constitute the minimum amount of requirements necessary to implement the SHOP program and accomplish our policy goals, and that no appropriate regulatory alternatives could be developed to further lessen the compliance burden.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule that includes any Federal mandate that may result in expenditures in any 1 year by State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately $146 million. Although we have not been able to quantify all costs, the combined administrative cost and user fee impact on State, local, or Tribal governments and the private sector may be above the threshold. Earlier portions of this RIA constitute our UMRA analysis.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. Because States have flexibility in designing their Exchanges and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. For States that elected to operate an Exchange or, risk adjustment program, much of the initial cost of creating these programs were funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In HHS's view, while this proposed rule would not impose substantial direct requirement costs on State and local governments, this regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. However, HHS anticipates that the Federalism implications (if any) are substantially mitigated because under the statute and our proposals, States have choices regarding the structure, governance, and operations of their Exchanges and risk adjustment program. For example, our proposals relating to binder payment rules and termination of coverage are intended to provide State Exchanges with significant flexibility. Additionally, the Affordable Care Act does not require States to establish these programs; if a State elects not to establish any of these programs or is not approved to do so, HHS must establish and operate the programs in that State. Additionally, States have the option to establish and operate their own SHOP without also establishing and operating their own individual market Exchange. Our proposals requiring SBE–FPs to establish requirements that are consistent with certain Federal requirements when using the Federal platform for certain SHOP functions would not apply should the State decide not to use the Federal platform for these SHOP functions.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, HHS has engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with State insurance officials on an individual basis.

While developing this proposed rule, HHS has attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide access to Affordable Insurance Exchanges for consumers in every State. By doing so, it is HHS's view that we have complied with the requirements of Executive Order 13132.

States will continue to license, monitor, and regulate agents and brokers, both inside and outside of Exchanges. All State laws related to agents and brokers, including State laws related to appointments, contractual relationships with issuers, licensing, marketing, conduct, and fraud will continue to apply.

H. Congressional Review Act

This proposed rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to Congress and the Comptroller for review.

List of Subjects

45 CFR Parts 144, 146, and 147

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

45 CFR Part 154

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interest, Consumer protection, Grant administration, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, American Indian/Alaska Natives, Conflict of interest, Consumer protection, Cost-sharing reductions, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Individuals with disabilities, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

45 CFR Part 157

Employee benefit plans, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR parts 144, 146, 147, 148, 153, 154, 155, 156, 157 and 158 as set forth below.

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 1. The authority citation for part 144 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act, 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92.

■ 2. Section 144.103 is amended by revising the introductory text of the definition of "plan" and by revising the definition of "product" to read as follows:

§ 144.103 Definitions.

* * * * *

Plan means, with respect to a product, the pairing of the health insurance coverage benefits under the product with a particular cost-sharing structure, provider network, and service area. The product comprises all plans offered with those characteristics and the combination of the service areas for all plans offered within a product constitutes the total service area of the product. With respect to a plan that has been modified at the time of coverage renewal consistent with § 147.106 of this subchapter—

* * * * *

Product means a discrete package of health insurance coverage benefits that are offered using a particular product network type (such as health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity) within a service area. In the case of a product that has been modified, transferred, or replaced, the new product will be considered to be the same as the modified, transferred, or replaced product when the changes to the modified, transferred, or replaced product meet the standards of § 146.152(f), § 147.106(e), or § 148.122(g) of this subchapter (relating to uniform modification of coverage), as applicable.

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PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 3. The authority citation for part 146 continues to read as follows:

Authority: Secs. 2702 through 2705, 2711 through 2723, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92).

■ 4. Section 146.152 is amended by adding paragraph (d)(3) and revising paragraph (f)(3)(i) to read as follows:

§ 146.152 Guaranteed renewability of coverage for employers in the group market.

* * * * *

(d) * * *

(3) For purposes of this paragraph (d), subject to applicable State law, an issuer is not considered to have discontinued offering all health insurance coverage in a market if—

(i) The issuer or a member of the issuer's controlled group continues to offer and make available in the applicable market in the State at least one product of the issuer that is considered to be the same product as a product the issuer had been offering (as defined in § 144.103 of this subchapter). For purposes of this section, the term controlled group means a group of two or more persons that is treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended; or

(ii) The issuer continues to offer and make available at least one product in the applicable market in the State, even if such product is not considered to be the same product as a product the issuer had been offering (as defined in § 144.103 of this subchapter), provided the issuer subjects that product to the rate review requirements under part 154 of this title (to the extent otherwise applicable to coverage of the same type and in the same market) as if that part applied to that product, and reasonably identifies a discontinued product that corresponds to the new product for purposes of such rate review.

* * * * *

(f) * * *

(3) * * *

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act), or a member of the issuer's controlled group (as defined in paragraph (d) of this section);

* * * * *

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 5. The authority citation for part 147 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 6. Section 147.102 is amended by revising paragraphs (d)(1) and (e) to read as follows:

§ 147.102 Fair health insurance premiums.

* * * * *

(d) * * *

(1) *Child age bands.* (i) A single age band for individuals age 0 through 14.

(ii) One-year age bands for individuals age 15 through 20.

* * * * *

(e) *Uniform age rating curves.* Each State may establish a uniform age rating curve in the individual or small group market, or both markets, for rating purposes under paragraph (a)(1)(iii) of this section. If a State does not establish a uniform age rating curve or provide information on such age curve in accordance with § 147.103, a default uniform age rating curve specified in guidance by the Secretary to reflect market patterns in the individual and small group markets will apply in that State that takes into account the rating variation permitted for age under State law.

* * * * *

■ 7. Section 147. 104 is amended by revising paragraph (b)(2) to read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(b) * * *

(2) *Limited open enrollment periods.* A health insurance issuer in the individual market must provide a limited open enrollment period for the events described in § 155.420(d) of this subchapter, excluding §§ 155.420(d)(3) of this subchapter (concerning citizenship status), 155.420(d)(8) of this subchapter (concerning Indians), 155.420(d)(9) of this subchapter (concerning exceptional circumstances), and 155.420(d)(13) of this subchapter (concerning eligibility for insurance affordability programs or enrollment in the Exchange).

* * * * *

■ 8. Section 147.106 is amended by adding paragraph (d)(3) and revising paragraphs (e)(3)(i) to read as follows:

§ 147.106 Guaranteed renewability of coverage.

* * * * *

(d) * * *

(3) For purposes of this paragraph (d), subject to applicable State law, an issuer is not considered to have discontinued offering all health insurance coverage in a market if—

(i) The issuer or a member of the issuer's controlled group continues to offer and make available in the applicable market in the State at least one product of the issuer that is considered to be the same product as a product the issuer had been offering (as defined in § 144.103 of this subchapter). For purposes of this section, the term controlled group means a group of two or more persons that is treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended; or

(ii) The issuer continues to offer and make available at least one product in the applicable market in the State, even if such product is not considered to be the same product as a product the issuer had been offering (as defined in § 144.103 of this subchapter), provided the issuer subjects that product to the rate review requirements under part 154 of this title (to the extent otherwise applicable to coverage of the same type and in the same market) as if that part applied to that product, and reasonably identifies a discontinued product that corresponds to the new product for purposes of such rate review.

(e) * * *

(3) * * *

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act) or member of the issuer's controlled group (as defined in paragraph (d) of this section);

* * * * *

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

■ 9. The authority citation for part 148 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791 and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 10. Section 148.122 is amended by adding paragraph (e)(4) and revising paragraph (g)(3)(i) to read as follows:

§ 148.122 Guaranteed renewability of individual health insurance coverage.

* * * * *

(e) * * *

(4) For purposes of this paragraph (e), subject to applicable State law, an issuer is not considered to have discontinued offering all health insurance coverage in a market if—

(i) The issuer or a member of the issuer's controlled group continues to offer and make available in the applicable market in the State at least one product of the issuer that is considered to be the same product as a product the issuer had been offering (as defined in § 144.103 of this subchapter). For purposes of this section, the term controlled group means a group of two or more persons that is treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended; or

(ii) The issuer continues to offer and make available at least one product in the applicable market in the State, even if such product is not considered to be the same product as a product the issuer had been offering (as defined in § 144.103 of this subchapter), provided the issuer subjects that product to the rate review requirements under part 154 of this title (to the extent otherwise applicable to coverage of the same type and in the same market) as if that part applied to that product, and reasonably identifies a discontinued product that corresponds to the new product for purposes of such rate review.

* * * * *

(g) * * *

(3) * * *

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act) or member of the issuer's controlled group (as defined in paragraph (e) of this section);

* * * * *

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 11. The authority citation for part 153 continues to read as follows:

Authority: Secs. 1311, 1321, 1341–1343, Pub. L. 111–148, 24 Stat. 119.

§ 153.20 [Amended]

■ 12. Section 153.20 is amended by removing the definition of "Large employer".

■ 13. Section 153.320 is amended by revising paragraphs (a)(1) and (b)(1)(i) to read as follows:

§ 153.320 Federally certified risk adjustment methodology.

(a) * * *

(1) The risk adjustment methodology is developed by HHS and published in advance of the benefit year in rulemaking; or

* * * * *

(b) * * *

(1) * * *

(i) Draft factors to be employed in the model, including but not limited to demographic factors, diagnostic factors, and utilization factors, if any, the dataset(s) to be used to calculate final coefficients, and the date by which final coefficients will be released in guidance;

* * * * *

■ 14. Section 153.610 is amended by revising paragraph (f)(2) to read as follows:

§ 153.610 Risk adjustment issuer requirements.

* * * * *

(f) * * *

(2) Remit to HHS an amount equal to the product of its monthly billable enrollment in the risk adjustment covered plan multiplied by the per-enrollee-per-month risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

■ 15. Section 153.630 is amended by—

■ a. Redesignating paragraphs (b)(7)(iii) and (iv) as paragraphs (b)(7)(iv) and (v), respectively;

■ b. Adding a new paragraph (b)(7)(iii); and

■ c. Revising paragraph (d).

The addition and revision read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

* * * * *

(b) * * *

(7) * * *

(iii) Beginning in the 2018 benefit year, validating enrollee health status through review of all relevant paid pharmacy claims;

* * * * *

(d) *Risk adjustment data validation disputes and appeals.* (1) Within 15 calendar days of notification of the initial validation audit sample determined by HHS, in the manner set forth by HHS, an issuer must confirm the sample or file a discrepancy report to dispute the initial validation audit sample determined by HHS.

(2) Within 30 calendar days of notification of the findings of a second validation audit or the calculation of a risk score error rate, in the manner set forth by HHS, an issuer must confirm the audit or error rate, or file a discrepancy report to dispute the findings of a second validation audit or the calculation of a risk score error rate as result of risk adjustment data validation.

(3) An issuer may appeal the findings of a second validation audit or the calculation of a risk score error rate as result of risk adjustment data validation, under the process set forth in § 156.1220 of this subchapter.

* * * * *

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

■ 16. The authority citation for part 154 continues to read as follows:

Authority: Section 2794 of the Public Health Service Act (42 U.S.C. 300gg–94).

■ 17. Section 154.102 is amended by revising the definition of "product" to read as follows:

§ 154.102 Definitions.

* * * * *

Product means a package of health insurance coverage benefits with a discrete set of rating and pricing methodologies offered in a State. The term product includes any product that is discontinued and newly filed within a 12-month period when the changes to the product meet the standards of § 147.106(e)(2) or (3) of this subchapter (relating to uniform modification of coverage).

* * * * *

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 18. The authority citation for part 155 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1332, 1334, 1402, 1411, 1412, 1413, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083).

■ 19. Section 155.20 is amended by revising the definition of "standardized option" to read as follows:

§ 155.20 Definitions.

* * * * *

Standardized option means a QHP offered for sale through an individual market Exchange that either—

(1) Has a standardized cost-sharing structure specified by HHS in rulemaking; or

(2) Is a high deductible health plan with a standardized cost-sharing structure specified by HHS in rulemaking or in HHS guidance issued solely to modify the cost-sharing structure specified by HHS in rulemaking to the extent necessary to align with high deductible health plan requirements under section 223 of the Internal Revenue Code of 1986, as amended, and HHS actuarial value requirements.

* * * * *

■ 20. Section 155.200 is amended by adding paragraph (f)(4) to read as follows:

§ 155.200 Functions of an Exchange.

* * * * *

(f) * * *

(4) A State Exchange on the Federal platform that utilizes the Federal platform for certain SHOP functions, as set forth in paragraphs (f)(4)(i) through (vii), must—

(i) If utilizing the Federal platform for SHOP eligibility, enrollment, or premium aggregation functions, establish standard processes for premium calculation, premium payment, and premium collection that are consistent with the requirements applicable in a Federally-facilitated SHOP under § 155.705(b)(4);

(ii) If utilizing the Federal platform for SHOP enrollment or premium aggregation functions, require its QHP issuers to make any changes to rates in accordance with the timeline applicable in a Federally-facilitated SHOP under § 155.705(b)(6)(i)(A);

(iii) If utilizing the Federal platform for SHOP enrollment functions, establish minimum participation rate requirements and calculation methodologies that are consistent with those applicable in a Federally-facilitated SHOP under § 155.705(b)(10);

(iv) If utilizing the Federal platform for SHOP enrollment or premium aggregation functions, establish employer contribution methodologies that are consistent with the methodologies applicable in a Federally-facilitated SHOP under § 155.705(b)(11)(ii);

(v) If utilizing the Federal platform for SHOP enrollment functions, establish annual employee open enrollment period requirements that are consistent with § 155.725(e)(2);

(vi) If utilizing the Federal platform for SHOP enrollment functions, establish effective dates of coverage for an initial group enrollment or a group renewal that are consistent with the effective dates of coverage applicable in a Federally-facilitated SHOP under § 155.725(h)(2); and

(vii) If utilizing the Federal platform for SHOP eligibility, enrollment, or premium aggregation functions, establish policies for the termination of SHOP coverage or enrollment that are consistent with the requirements applicable in a Federally-facilitated SHOP under § 155.735.

■ 21. Section 155.205 is amended by revising paragraphs (c)(2)(iii)(A) and (B) to read as follows:

§ 155.205 Consumer assistance tools and programs of an Exchange.

* * * * *

(c) * * *

(2) * * *

(iii) * * *

(A) For Exchanges and QHP issuers, beginning no later than the first day of the individual market open enrollment period for the 2017 benefit year, this standard also includes taglines on Web site content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. A document is deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if it is required to be provided by law or regulation to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States, as determined in guidance published by the Secretary. If an Exchange is operated by an entity operating multiple Exchanges, or relies on an eligibility or enrollment platform that is relied on by multiple Exchanges, the Exchange may aggregate the limited English proficient populations across all the States served by the entity that operates the Exchange or its eligibility or enrollment platform to determine the top 15 languages required for taglines. A QHP issuer may aggregate the limited English proficient populations across all States served by the health insurance issuers within the issuer's controlled group (as defined under § 147.106(d)(3)(i) of this subchapter), whether or not those health insurance issuers offer plans through the Exchange in each of those States, to determine the top 15 languages required for taglines. Exchanges and QHP issuers may satisfy tagline requirements with respect to Web site content if they post a Web link prominently on their home page that directs individuals to the full text of the taglines indicating how individuals may obtain language assistance services, and if they also include taglines on any critical standalone document linked to or embedded in the Web site.

(B) For an agent or broker subject to § 155.220(c)(3)(i), beginning on the first day of the individual market open enrollment period for the 2017 benefit year, or when such entity has been registered with the Exchange for at least 1 year, whichever is later, this standard also includes taglines on Web site content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. A document is deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if it is required to be provided by law or regulation to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States, as determined in guidance published by the Secretary. An agent or broker subject to § 155.220(c)(3)(i) that is licensed in and serving multiple States may aggregate the limited English populations in the States it serves to determine the top 15 languages required for taglines. An agent or broker subject to § 155.220(c)(3)(i) may satisfy tagline requirements with respect to Web site content if it posts a Web link prominently on its home page that directs individuals to the full text of the taglines indicating how individuals may obtain language assistance services, and if it also includes taglines on any critical standalone document linked to or embedded in the Web site.

* * * * *

■ 22. Section 155.220 is amended by:

■ a. Revising paragraph (c)(3)(i)(E);

■ b. Removing the word "and" at the end of paragraph (c)(3)(i)(F);

■ c. Removing the period at the end of paragraph (c)(3)(i)(G) and adding "; and" in its place;

■ d. Adding paragraphs (c)(3)(i)(H) through (M);

■ e. Revising paragraphs (c)(4)(i)(E); and

■ f. Revising paragraph (j)(2)(i).

The additions and revisions read as follows:

§ 155.220 Ability of States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(c) * * *

(3)(i) * * *

(E) Maintain audit trails and records in an electronic format for a minimum of ten years and cooperate with any audit under this section;

* * * * *

(H) Differentially display all standardized options in accordance with the requirements under § 155.205(b)(1) in a manner consistent with that adopted by HHS for display on the Federally-facilitated Exchange Web site, unless HHS approves a deviation;

(I) Prominently display information provided by HHS pertaining to a consumer's eligibility for advance payments of the premium tax credit or cost-sharing reductions;

(J) Allow the consumer to select an amount for advance payments of the premium tax credit, if applicable, and make related attestations in accordance with § 155.310(d)(2);

(K) Support post-enrollment activities necessary for the consumer to effectuate his or her coverage or resolve issues related to his or her enrollment, including discrepancies related to eligibility;

(L) Demonstrate operational readiness and compliance with applicable requirements prior to the agent or broker's Internet Web site being used to complete the QHP selection; and

(M) HHS may immediately suspend the agent or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS's satisfaction.

* * * * *

(4)(i) * * *

(E) Report to HHS and applicable State departments of insurance any potential material breach of the standards in paragraphs (c) and (d) of this section, or the agreement entered into under § 155.260(b), by the agent or broker accessing the Internet Web site, should it become aware of any such potential breach. An agent or broker that provides access to its Web site or ability to transact information with HHS to another agent or broker Web site is responsible for ensuring that the other agent's or broker's Web site is in compliance with this section; and

* * * * *

(j) * * *

(2)(i) Provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment Web site that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation;

* * * * *

■ 23. Section 155.230 is amended by revising paragraph (d)(2) and adding paragraph (d)(3) to read as follows:

§ 155.230 General standards for Exchange notices.

* * * * *

(d) * * *

(2) Unless otherwise required by Federal or State law, the SHOP must provide required notices electronically or, if an employer or employee elects, through standard mail. If notices are provided electronically, the SHOP must comply with the requirements for electronic notices in 42 CFR 435.918(b)(2) through (5) for the employer or employee.

(3) In the event that an individual market Exchange or SHOP is unable to send select required notices electronically due to technical limitations, it may instead send these notices through standard mail, even if an election has been made to receive such notices electronically.

■ 24. Section 155.330 is amended by revising paragraphs (d)(1)(ii), (e)(2)(i) introductory text, and (g)(1) and adding paragraph (e)(2)(iii) to read as follows:

§ 155.330 Eligibility redetermination during a benefit year.

* * * * *

(d) * * *

(1) * * *

(ii) For an enrollee on whose behalf advance payments of the premium tax credit or cost-sharing reductions are being provided, eligibility determinations for or enrollment in Medicare, Medicaid, CHIP, or the Basic Health Program, if a Basic Health Program is operating in the service area of the Exchange.

* * * * *

(e) * * *

(2) * * *

(i) Except as provided in paragraph (e)(2)(iii) of this section, if the Exchange identifies updated information regarding death, in accordance with paragraph (d)(1)(i) of this section, or regarding any factor of eligibility not regarding income, family size, or family composition, or tax filing status, the Exchange must—

* * * * *

(iii) If the Exchange identifies updated information that the tax filer for the enrollee's household or the tax filer's spouse did not comply with the requirements described in § 155.305(f)(4), the Exchange when redetermining and providing notification of eligibility for advance payments of the premium tax credit must:

(A) Follow the procedures specified in paragraph (e)(2)(i) of this section;

(B) Follow the procedures in guidance published by the Secretary; or

(C) Follow alternative procedures approved by the Secretary based on a showing by the Exchange that the alternative procedures would facilitate continued enrollment in coverage with financial assistance for which the enrollee remains eligible, provide appropriate information about the process to the enrollee (including regarding any action by the enrollee necessary to obtain the most accurate redetermination of eligibility), and provide adequate program integrity protections and safeguards for Federal tax information under section 6103 of the Internal Revenue Code with respect to the confidentiality, disclosure, maintenance, or use of such information.

* * * * *

(g) * * *

(1) When an eligibility redetermination in accordance with this section results in a change in the amount of advance payments of the premium tax credit for the benefit year, the Exchange must:

(i) Recalculate the amount of advance payments of the premium tax credit in such a manner as to account for any advance payments already made on behalf of the tax filer for the benefit year for which information is available to the Exchange, such that the recalculated advance payment amount is projected to result in total advance payments for the benefit year that correspond to the tax filer's total projected premium tax credit for the benefit year, calculated in accordance with 26 CFR 1.36B–3 (or, if less than zero, be set at zero); or

(ii) For benefit years through 2023, recalculate advance payments of the premium tax credit using an alternate method that has been approved by the Secretary.

* * * * *

■ 25. Section 155.400 is amended by adding paragraph (e)(2) to read as follows:

§ 155.400 Enrollment of qualified individuals into QHPs.

* * * * *

(e) * * *

(2) *Premium payment deadline extension.* Exchanges may, and the Federally-facilitated Exchange will, allow issuers experiencing billing or enrollment problems due to high volume or technical errors to implement a reasonable extension of the binder payment deadlines in paragraph (e)(1) of this section.

* * * * *

■ 26. Section 155.420 is amended by:

■ a. Revising paragraphs (b)(2)(iii), (d)(1)(i) and (iii), and (d)(8);

■ b. Removing the period at the end of paragraph (d)(10) and adding a semicolon in its place; and

■ c. Adding paragraphs (d)(10), (11), (12), and (13).

The revisions and additions read as follows:

§ 155.420 Special enrollment periods.

* * * * *

(b) * * *

(2) * * *

(iii) In the case of a qualified individual or enrollee eligible for a special enrollment period as described in paragraph (d)(4), (5), (9), (11), (12), or (13) of this section, the Exchange must ensure that coverage is effective on an appropriate date based on the circumstances of the special enrollment period.

* * * * *

(d) * * *

(1) * * *

(i) Loses minimum essential coverage. The date of the loss of coverage is the last day the consumer would have coverage under his or her previous plan or coverage;

* * * * *

(iii) Loses pregnancy-related coverage described under section 1902(a)(10)(A)(i)(IV) and (a)(10)(A)(ii)(IX) of the Act (42 U.S.C. 1396a(a)(10)(A)(i)(IV), (a)(10)(A)(ii)(IX)). The date of the loss of coverage is the last day the consumer would have pregnancy-related coverage; or

* * * * *

(8) The qualified individual—

(i) Who gains or maintains status as an Indian, as defined by section 4 of the Indian Health Care Improvement Act, may enroll in a QHP or change from one QHP to another one time per month; or

(ii) Who is or becomes a dependent of an Indian, as defined by section 4 of the Indian Health Care Improvement Act and is enrolled or is enrolling in a QHP through an Exchange on the same application as the Indian, may change from one QHP to another one time per month, at the same time as the Indian;

* * * * *

(10) A qualified individual or enrollee—

(i) Is a victim of domestic abuse or spousal abandonment, as defined by 26 CFR 1.36B–2T, as amended, including a dependent or unmarried victim within a household, is enrolled in minimum essential coverage and seeks to enroll in coverage separate from the perpetrator of the abuse or abandonment; or

(ii) Is a dependent of a victim of domestic abuse or spousal abandonment, on the same application as the victim, may enroll in coverage at the same time as the victim;

(11) A qualified individual or dependent—

(i) Applies for coverage on the Exchange during the annual open enrollment period or due to a qualifying life event, is assessed by the Exchange as potentially eligible for Medicaid or the Children's Health Insurance Program (CHIP), and is determined ineligible for Medicaid or CHIP by the State Medicaid or CHIP agency either after open enrollment has ended or more than 60 days after the qualifying event; or

(ii) Applies for coverage at the State Medicaid or CHIP agency during the annual open enrollment period, and is determined ineligible for Medicaid or CHIP after open enrollment has ended;

(12) The qualified individual or enrollee, or his or her dependent, adequately demonstrates to the Exchange that a material error related to plan benefits, service area, or premium influenced the qualified individual's or enrollee's decision to purchase a QHP; or

(13) At the option of the Exchange, the qualified individual provides satisfactory documentary evidence to verify his or her eligibility for an insurance affordability program or enrollment in a qualified health plan through the Exchange following termination of Exchange enrollment due to a failure to verify such status within the time period specified in § 155.315 or is under 100 percent of the Federal poverty level and did not enroll in coverage while waiting for HHS to verify his or her citizenship, status as a national, or lawful presence.

* * * * *

■ 27. Section 155.430 is amended by revising paragraph (b)(2)(iii) to read as follows:

§ 155.430 Termination of Exchange enrollment or coverage.

* * * * *

(b) * * *

(2) * * *

(iii) The enrollee's coverage is rescinded in accordance with § 147.128 of this subchapter, after a QHP issuer demonstrates, to the reasonable satisfaction of the Exchange, if required by the Exchange, that the rescission is appropriate;

* * * * *

■ 28. Section 155.505 is amended by adding paragraph (h) to read as follows:

§ 155.505 General eligibility appeals requirements.

* * * * *

(h) *Electronic requirements.* If the Exchange appeals entity cannot fulfill the electronic requirements of subparts C, D, F, and H of this part related to acceptance of telephone- or Internet-based appeal requests, the provision of appeals notices electronically, or the secure electronic transfer of eligibility and appeal records between appeals entities and Exchanges or Medicaid or CHIP agencies, the Exchange appeals entity may fulfill those requirements that it cannot fulfill electronically using a secure and expedient paper-based process.

■ 29. Section 155.555 is amended by revising paragraph (b) to read as follows:

§ 155.555 Employer appeals process.

* * * * *

(b) *Exchange employer appeals process.* An Exchange may establish an employer appeals process in accordance with the requirements of this section and §§ 155.505(f) through (h) and 155.510(a)(1) and (2) and (c). Where an Exchange has not established an employer appeals process, HHS will provide an employer appeals process that meets the requirements of this section and §§ 155.505(f) through (h) and 155.510(a)(1) and (2) and (c).

* * * * *

■ 30. Section 155.725 is amended by revising paragraphs (g)(1) and (2) and (j)(2)(i) and adding paragraph (g)(3) to read as follows:

§ 155.725 Enrollment periods under SHOP.

* * * * *

(g) * * *

(1) The SHOP must provide an employee who becomes a qualified employee outside of the initial or annual open enrollment period with a 30-day enrollment period beginning on the date the qualified employer notifies the SHOP about the newly qualified employee. Qualified employers must notify the SHOP about a newly qualified employee on or before the thirtieth day after the day that the employee becomes eligible for coverage.

(2) The effective date of coverage for a QHP selection received by the SHOP from a newly qualified employee is the first day of the month following plan selection, unless the employee is subject to a waiting period consistent with § 147.116 of this subchapter and paragraph (g)(3) of this section, in which case the effective date will be on the first day of the month following the end of the waiting period, but in no case may the effective date fail to comply with § 147.116 of this subchapter. If a newly qualified employee's waiting period ends on the first day of a month and the employee has already made a plan selection by that date, coverage must take effect on that date. If a newly qualified employee makes a plan selection on the first day of a month and any applicable waiting period has ended by that date, coverage must be effective on that date. If a qualified employer with variable hour employees makes regularly having a specified number of hours of service per period, or working full-time, a condition of employee eligibility for coverage offered through a SHOP, any measurement period that the qualified employer elects to use under § 147.116(c)(3)(i) to determine whether an employee meets the applicable eligibility conditions with respect to coverage offered through the SHOP must not exceed 10 months, beginning on any date between the employee's start date and the first day of the first calendar month following the employee's start date.

(3) Waiting periods in a SHOP are calculated beginning on the date the employee becomes eligible for coverage, regardless of when a qualified employer notifies the SHOP about the newly qualified employee, and must not exceed 60 days in length. Waiting periods in a Federally-facilitated SHOP or a State-based SHOP that uses the Federal platform for SHOP eligibility or enrollment functions must be 0, 15, 30, 45 or 60 days in length.

* * * * *

(j) * * *

(2) * * *

(i) Experiences an event described in § 155.420(d)(1) (other than paragraph (d)(1)(ii)), or experiences an event described in § 155.420(d)(2), (4), (5), (7), (8), (9), (10), (11), or (12);

* * * * *

■ 31. Section 155.740 is amended by revising paragraph (b)(2) to read as follows:

§ 155.740 SHOP employer and employee eligibility appeals requirements.

* * * * *

(b) * * *

(2) The appeals entity must conduct appeals in accordance with the requirements established in this section and §§ 155.505(e) through (h) and 155.510(a)(1) and (2) and (c).

* * * * *

■ 32. Section 155.1090 is added to subpart K to read as follows:

§ 155.1090 Request for reconsideration.

(a) *Request for reconsideration of denial of certification specific to a Federally-facilitated Exchange*—(1) *Request for reconsideration.* The Federally-facilitated Exchanges will permit an issuer that has submitted a complete application to a Federally-facilitated Exchange for certification of a health plan as a QHP and is denied certification to request reconsideration of such action.

(2) *Form and manner of request.* An issuer submitting a request for reconsideration under paragraph (a)(1) of this section must submit a written request for reconsideration to HHS, in the form and manner specified by HHS, within 7 calendar days of the date of the written notice of denial of certification. The issuer must include any and all documentation the issuer wishes to provide in support of its request with its request for reconsideration.

(3) *HHS reconsideration decision.* HHS will provide the issuer with a written notice of the reconsideration decision. The decision will constitute HHS's final determination.

(b) [Reserved]

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 33. The authority citation for part 156 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1313, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

■ 34. Section 156.80 is amended by revising paragraph (d)(1) to read as follows:

§ 156.80 Single risk pool.

* * * * *

(d) * * *

(1) *In general.* A health insurance issuer must establish an index rate that is effective January 1 of each calendar year for a State market described in paragraphs (a) through (c) of this section.

(i) The index rate must be based on the total combined claims costs for providing essential health benefits within the single risk pool of that State market.

(ii) The index rate must be adjusted on a market-wide basis for the State based on the total expected market-wide payments and charges under the risk adjustment program and Exchange user fees (expected to be remitted under § 156.50(b) or (c) and (d) as applicable plus the dollar amount under § 156.50(d)(3)(i) and (ii) expected to be credited against user fees payable for that State market).

(iii) The index rate must be calibrated on a market-wide basis to correspond to an age rating factor of 1.0, a geographic rating factor of 1.0, and a tobacco use rating factor of 1.0, in a manner specified by the Secretary in guidance.

(iv) The premium rate for all of the health insurance issuer's plans in the relevant State market must use the applicable market-wide adjusted index rate, subject only to the plan-level adjustments permitted in paragraph (d)(2) of this section.

* * * * *

■ 35. Section 156.140 is amended by revising paragraph (c) to read as follows:

§ 156.140 Levels of coverage.

* * * * *

(c) *De minimis variation.* The allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan is ±2 percentage points, except if a health plan under paragraph (b)(1) of this section (a bronze health plan) either covers and pays for at least one major service, other than preventive services, before the deductible or meets the requirements to be a high deductible high plan within the meaning of 26 U.S.C. 223(c)(2), in which case the allowable variation in AV for such plan is −2 percentage points and +5 percentage points.

■ 36. Section 156.200 is amended by revising paragraph (c)(1) to read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(c) * * *

(1) At least one QHP in the silver coverage level and at least one QHP in the gold coverage level as described in § 156.140 throughout each service area in which it offers coverage through the Exchange; and,

* * * * *

■ 37. Section 156.235 is amended by revising paragraphs (a)(2)(i) and (b)(2)(i) to read as follows:

§ 156.235 Essential community providers.

(a) * * *

(2) * * *

(i) The network includes as participating practitioners at least a minimum percentage, as specified by HHS, of available essential community providers in each plan's service area. Multiple providers at a single location will count as a single essential community provider toward both the available essential community providers in the plan's service area and the issuer's satisfaction of the essential community provider participation standard; and

* * * * *

(b) * * *

(2) * * *

(i) The number of its providers that are located in Health Professional Shortage Areas or five-digit zip codes in which 30 percent or more of the population falls below 200 percent of the Federal Poverty Line satisfies a minimum percentage, specified by HHS, of available essential community providers in the plan's service area. Multiple providers at a single location will count as a single essential community provider toward both the available essential community providers in the plan's service area and the issuer's satisfaction of the essential community provider participation standard; and

* * * * *

■ 38. Section 156.265 is amended by:

■ a. Removing the word "and" at the end of paragraph (b)(3)(ii);

■ b. Removing the period at the end of paragraph (b)(3)(iii) and adding "; and" in its place; and

■ c. Adding paragraph (b)(3)(iv).

The addition reads as follows:

§ 156.265 Enrollment process for qualified individuals.

* * * * *

(b) * * *

(3) * * *

(iv) Differentially display all standardized options in accordance with the requirements under § 155.205(b)(1) of this subchapter in a manner consistent with that adopted by HHS for display on the Federally-facilitated Exchange Web site, unless HHS approves a deviation.

* * * * *

■ 39. Section 156.272 is added to read as follows:

§ 156.272 Issuer participation for full plan year.

(a) An issuer offering a QHP through an individual market Exchange must make the QHP available for enrollment through the Exchange for the full plan year for which the plan was certified, including to eligible enrollees during limited open enrollment periods, unless a basis for suppression applies under § 156.815.

(b) Unless a basis for suppression under section 156.815 applies, an issuer offering a QHP through a SHOP must make the QHP available for enrollment through the SHOP for the full plan year for which the QHP was certified.

(c) An issuer offering a QHP through a Federally-facilitated Exchange or a Federally-facilitated SHOP that does not comply with paragraph (a) or (b) of this section may, at the discretion of HHS, be precluded from offering QHPs in a Federally-facilitated Exchange or Federally-facilitated SHOP for up to the two succeeding plan years.

■ 40. Section 156.290 is amended by revising the section heading and paragraphs (a) introductory text and (b) to read as follows:

§ 156.290 Non-certification and decertification of QHPs.

(a) *Non-certification for a subsequent, consecutive certification cycle.* If a QHP issuer elects not to seek certification for a subsequent, consecutive certification cycle with the Exchange, the QHP issuer, at a minimum, must—

* * * * *

(b) *Notice of QHP non-certification for a subsequent, consecutive certification cycle.* (1) If a QHP issuer elects not to seek certification for a subsequent, consecutive certification cycle with the Exchange for its QHP, the QHP issuer must provide written notice to each enrollee.

(2) If a QHP issuer is denied certification for a subsequent, consecutive certification cycle by the Exchange, it must provide written notice to each enrollee within 30 days of the Exchange's denial of certification.

* * * * *

■ 41. Section 156.350 is amended by revising paragraph (a)(2) to read as follows:

§ 156.350 Eligibility and enrollment standards for Qualified Health Plan issuers on State-based Exchanges on the Federal platform.

(a) * * *

(2) Section 156.285(c)(5) and (c)(8)(iii) regarding the enrollment process for SHOP; and

* * * * *

■ 42. Section 156.430 is amended by adding paragraph (h) to read as follows:

§ 156.430 Payment for cost-sharing reductions.

* * * * *

(h) *Reconciliation of the cost-sharing reduction portion of advance payments discrepancies and appeals.* (1) If an issuer reports a discrepancy and seeks to dispute the notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments, it must report the discrepancy to HHS within 30 calendar days of notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments as described in paragraph (e) of this section, in the manner set forth by HHS.

(2) An issuer may appeal the amount of reconciliation of the cost-sharing reduction portion of advance payments, under the process set forth in § 156.1220.

■ 43. Section 156.715 is amended by adding paragraph (f) to read as follows:

§ 156.715 Compliance reviews of QHP issuer in Federally-facilitated Exchanges.

* * * * *

(f) *Failure to comply.* A QHP issuer that fails to comply with a compliance review under this section may be subject to enforcement remedies under subpart I of this part.

■ 44. Section 156.1220 is amended by—

■ a. Removing the word "or" at the end of paragraph (a)(1)(v);

■ b. Removing the period at the end of paragraph (a)(1)(vi) and adding "; or" in its place;

■ c. Adding paragraph (a)(1)(vii) and (viii); and

■ d. Revising paragraphs (a)(2), (a)(3)(ii), and (a)(4)(ii).

The revisions and additions read as follows:

§ 156.1220 Administrative appeals.

(a) * * *

(1) * * *

(vii) The findings of a second validation audit as a result of risk adjustment data validation with respect to risk adjustment data for the 2016 benefit year and beyond; or

(viii) The calculation of a risk score error rate as a result of risk adjustment data validation with respect to risk adjustment data for the 2016 benefit year and beyond.

(2) *Materiality threshold.* Notwithstanding paragraph (a)(1) of this section, an issuer may file a request for reconsideration under this section only if the amount in dispute under paragraph (a)(1)(i) through (viii) of this section, as applicable, is equal to or exceeds 1 percent of the applicable payment or charge listed in that paragraph (a)(1)(i) through (viii) payable to or due from the issuer for the benefit year, or $10,000, whichever is less.

(3) * * *

(ii) For a risk adjustment payment or charge, including an assessment of risk adjustment user fees, the findings of a second validation audit, or the calculation of a risk score error rate as a result of risk adjustment data validation, within 30 calendar days of the date of the notification under § 153.310(e) of this subchapter;

* * * * *

(4) * * *

(ii) Notwithstanding paragraph (a)(1) of this section, a reconsideration with respect to a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error may be requested only if, to the extent the issue could have been previously identified, the issuer notified HHS of the dispute through the applicable process for reporting a discrepancy set forth in §§ 153.630(d)(2), 153.710(d)(2), and 156.430(h)(1) of this subchapter, it was so identified and remains unresolved.

* * * * *

■ 45. Section 156.1230 is amended by adding paragraphs (b)(1), (2), and (3) to read as follows:

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

* * * * *

(b) * * *

(1) HHS may immediately suspend the QHP issuer's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS's satisfaction.

(2) The QHP issuer must demonstrate operational readiness and compliance with applicable requirements prior to the QHP issuer's Internet Web site being used to complete a QHP selection.

(3) The QHP issuer must provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment Web site that HHS

determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation.

■ 46. Section 156.1256 is revised to read as follows:

§ 156.1256 Other notices.

As directed by a Federally-facilitated Exchange, a health insurance issuer that is offering QHP coverage through a Federally-facilitated Exchange or a State-based Exchange on the Federal platform must notify its enrollees of material plan or benefit display errors and the enrollees' eligibility for a special enrollment period, included in § 155.420(d)(12) of this subchapter, within 30 calendar days after being notified by a Federally-facilitated Exchange that the error has been fixed, if directed to do so by a Federally-facilitated Exchange.

PART 157—EMPLOYER INTERACTIONS WITH EXCHANGES AND SHOP PARTICIPATION

■ 47. The authority citation for part 157 continues to read as follows:

Authority: Title I of the Affordable Care Act, Sections 1311, 1312, 1321, 1411, 1412, Pub. L. 111–148, 124 Stat. 199.

■ 48. Section 157.205 is amended by revising paragraph (f)(1) to read as follows:

§ 157.205 Qualified employer participation in a SHOP.

* * * * *

(f) * * *

(1) Newly eligible dependents and, on or before the thirtieth day after the day that the employee becomes eligible for coverage, newly qualified employees; and

* * * * *

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 49. The authority citation for part 158 continues to read as follows:

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18), as amended.

■ 50. Section 158.121 is revised to read as follows:

§ 158.121 Newer experience.

If, for any aggregation as defined in § 158.120, 50 percent or more of the total earned premium for an MLR reporting year is attributable to policies newly issued in that MLR reporting year, then the experience of these policies may be excluded from the report required under § 158.110 for that same MLR reporting year. If an issuer chooses to defer reporting of newer business as provided in this section, then the excluded experience must be added to the experience reported in the following MLR reporting year.

■ 51. Section 158.232 is amended by revising paragraphs (d)(1) and (2) and (e)(1) and (2) and adding paragraph (f) to read as follows:

§ 158.232 Calculating the credibility adjustment.

* * * * *

(d) * * *

(1) Each year in the aggregation included experience of at least 1,000 life-years; and

(2) The issuer's preliminary MLR, as defined under paragraph (f) of this section, for each year in the aggregation was below the applicable MLR standard, as established under §§ 158.210 and 158.211.

(e) * * *

(1) Each year in the aggregation included experience of at least 1,000 life-years; and

(2) The issuer's preliminary MLR, as defined under paragraph (f) of this section, for each year in the aggregation was below the applicable MLR standard, as established under §§ 158.210 and 158.211.

(f) *Preliminary MLR.* Preliminary MLR means the ratio of the numerator, as defined in § 158.221(b) and calculated as of March 31st of the year following the year for which the MLR report required in § 158.110 is being submitted, to the denominator, as defined in § 158.221(c), calculated using only a single year of experience, and without applying any credibility adjustment.

■ 52. Section 158.240 is amended by—

■ a. Revising paragraph (c)(1);

■ b. Redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively; and

■ c. Adding a new paragraph (d).

The revision and addition read as follows:

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

* * * * *

(c) * * *

(1) For each MLR reporting year, an issuer must rebate to the enrollee, subject to paragraph (d) of this section, the total amount of premium revenue, as defined in § 158.130, received by the issuer from the enrollee, after subtracting Federal and State taxes and licensing and regulatory fees as provided in §§ 158.161(a) and 158.162(a)(1) and (b)(1), and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance as provided in § 158.130(b)(5), multiplied by the difference between the MLR required by § 158.210 or § 158.211, and the issuer's MLR as calculated under § 158.221.

* * * * *

(d) *Limitation on total rebate payable for each year in the aggregation.* For any State and market, an issuer may elect to limit the amount of rebate payable for the MLR reporting year to the issuer's total outstanding rebate liability with respect to all years included in the aggregation. If an issuer elects this option, the outstanding rebate liability with respect to a specific year in the aggregation must be calculated by multiplying the denominator with respect to that year, as defined in § 158.221(c), by the difference between the MLR required by § 158.210 or § 158.211 for the MLR reporting year, and the sum of the issuer's preliminary MLR for that year, as defined under § 158.232(f), and the credibility adjustment applicable to the current MLR reporting year. The outstanding rebate liability with respect to a specific year must be reduced by any rebate payments applied against it in prior MLR reporting years. A rebate paid for an MLR reporting year must be applied first to reduce the outstanding rebate liability with respect to the earliest year in the aggregation.

* * * * *

Dated: August 11, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: August 24, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–20896 Filed 8–29–16; 4:15 pm]

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Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services
Office of the Inspector General
Administration for Children and Families

42 CFR Parts 3, 402, 403, et al.
45 CFR Parts 79, 93, 102, et al.
Adjustment of Civil Monetary Penalties for Inflation; Interim Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

42 CFR Part 3

Centers for Medicare & Medicaid Services

42 CFR Parts 402, 403, 411, 412, 422, 423, 460, 483, 488, and 493

Office of the Inspector General

42 CFR Part 1003

Office of the Secretary

45 CFR Parts 79, 93, 102, 147, 150, 155, 156, 158, and 160

Administration for Children and Families

45 CFR Part 303

RIN 0991–AC0

Adjustment of Civil Monetary Penalties for Inflation

AGENCY: Department of Health and Human Services, Office of the Assistant Secretary for Financial Resources, Centers for Medicare & and Medicaid Services, Office of the Inspector General, Administration for Children and Families.

ACTION: Interim final rule.

SUMMARY: The Department of Health and Human Services (HHS) is issuing a new regulation to adjust for inflation the maximum civil monetary penalty amounts for the various civil monetary penalty authorities for all agencies within HHS. We are taking this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. In addition, this interim final rule includes updates to certain agency-specific regulations to identify their updated information, and note the location of HHS-wide regulations.

DATES: This rule is effective on September 6, 2016.

FOR FURTHER INFORMATION CONTACT: Office of the Assistant Secretary for Financial Resources, Room 514–G, Hubert Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201; 202–690–6396; FAX 202–690–5405.

SUPPLEMENTARY INFORMATION:

I. Regulatory Information

The Department of Health and Human Services (HHS) is promulgating this interim final rule to ensure that the amount of civil monetary penalties authorized to be assessed or enforced by HHS reflect the statutorily mandated amounts and ranges as adjusted for inflation. Pursuant to Section 4(b) of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act), HHS is required to promulgate a "catch-up adjustment" through an interim final rule. Pursuant to the 2015 Act and 5 U.S.C. 553(b)(3)(B), HHS finds that good cause exists for immediate implementation of this interim final rule without prior notice and comment because it would be impracticable to delay publication of this rule for notice and comment. The 2015 Act specifies that the adjustments shall take effect not later than August 1, 2016. Additionally, the 2015 Act provides a clear formula for adjustment of the civil monetary penalties, leaving agencies little room for discretion. For these reasons, HHS finds that notice and comment would be impracticable in this situation. Additionally, if applicable, HHS agencies will update their civil monetary penalty-specific regulations to include a cross-reference to the revised regulations located at 45 CFR part 102 reflecting the new adjusted penalty amounts set out by HHS.[1]

II. Background and Requirements of the Law

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) (Sec. 701 of the Bipartisan Budget Act of 2015, Public Law 114–74, November 2, 2015), which amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) (Pub. L. 101–410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461 note 2(a)), to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. The 2015 Act, which removed an inflation update exclusion that previously applied to the Social Security Act as well as the Occupational Safety and Health Act, requires agencies to: (1) Adjust the level of civil monetary penalties with an initial "catch-up" adjustment through an interim final rulemaking (IFR); and (2) make subsequent annual adjustments for inflation.

The method of calculating inflation adjustments in the 2015 Act differs substantially from the methods used in past inflation adjustment rulemakings conducted pursuant to the Inflation Adjustment Act. Previously, adjustments to civil monetary penalties were conducted under rules that required significant rounding of figures. While this allowed penalties to be kept at round numbers, it meant that penalties would often not be increased at all if the inflation factor was not large enough. Furthermore, increases to penalties were capped at 10 percent. Over time, this formula caused penalties to lose value relative to total inflation.

The 2015 Act has removed these rounding rules; now, penalties are simply rounded to the nearest dollar. While this creates penalty values that are no longer round numbers, it does ensure that penalties will be increased each year to a figure commensurate with the actual calculated inflation. Furthermore, the 2015 Act "resets" the inflation calculations by excluding prior inflationary adjustments under the Inflation Adjustment Act, which contributed to a decline in the real value of penalty levels. To do this, the 2015 Act requires agencies to identify, for each penalty, the year and corresponding amount(s) for which the maximum penalty level or range of minimum and maximum penalties was established (*i.e.*, originally enacted by Congress) or last adjusted other than pursuant to the Inflation Adjustment Act.

In this rule, the adjusted civil penalty amounts are applicable only to civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015, the date of enactment of the 2015 Amendments. Therefore, violations occurring on or before November 2, 2015, and assessments made prior to August 1, 2016, whose associated violations occurred after November 2, 2015, will continue to be subject to the civil monetary penalty amounts set forth in the Department's existing regulations or as set forth by statute if the amount has not yet been adjusted by regulation.

Pursuant to the 2015 Act, the Department of Health and Human Services (HHS) has undertaken a thorough review of civil monetary penalties administered by its various components. This IFR sets forth the initial "catch-up" adjustment for civil monetary penalties as well as any necessary technical conforming changes to the language of the various regulations affected by this IFR. For each component, HHS has provided a table showing how the penalties are being increased pursuant to the 2015 Act. The first two columns ("Citation") identify the United States Code (U.S.C.) statutory citation, and the applicable regulatory citation in the Code of Federal Regulations (CFR), if any. The third column ("Description") provides a short description of the penalty. In the fourth column ("Pre-Inflation Penalty"), HHS has listed the penalty amount as it exists prior to the inflationary adjustments made by the effective date of this rule, and in the fifth column ("Date of Last Penalty Figure or Adjustment"), HHS has provided the amount and year of the penalty as enacted by Congress or changed through a mechanism other than pursuant to the Inflation Adjustment Act. In column six ("Percentage Increase"), HHS has listed the percentage increase based on the multiplier used to adjust from the CPI–U [2] of the year of enactment of the monetary penalty to the CPI–U for the current year, or a percentage equal to 150 percent, whichever is less. Multiplying the current penalty amount in column four by the percentage increase provides the "Increase" listed in column seven. The "Maximum Adjusted Penalty" in column eight is the sum of the current penalty amount and the "increase". Where applicable, some HHS agencies will make as soon as practicable conforming edits to regulatory text. Additionally, HHS is issuing new regulatory text including the table showing how the penalties are being increased under the 2015 Act, located at 45 CFR part 102, to implement the civil monetary penalty (CMP) amounts adjusted for inflation agency-wide. Additionally, the 2015 Act requires agencies to publish annual adjustments not later than January 15 of every year after publication of the initial adjustment.

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[1] All applicable civil monetary penalty authorities within the jurisdiction of HHS must be adjusted in accordance with the 2015 Act. Where existing HHS agency regulations setting forth civil monetary penalty amounts are not updated by this interim final rule, they will be amended in a separate action as soon as practicable.

CALCULATION OF CMP ADJUSTMENTS

Citation		Description [2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment [3]	Percentage increase [4]	Increase ($) [5]	Maximum adjusted penalty ($)
U.S.C.	CFR [1]						
21 U.S.C. (FDA):							
333(b)(2)(A)		Penalty for violations related to drug samples resulting in a conviction of any representative of manufacturer or distributor in any 10-year period.	50,000	1988	97.869	48,935	98,935
333(b)(2)(B)		Penalty for violation related to drug samples resulting in a conviction of any representative of manufacturer or distributor after the second conviction in any 10-yr period.	1,000,000	1988	97.869	978,690	1,978,690
333(b)(3)		Penalty for failure to make a report required by 21 U.S.C. 353(d)(3)(E) relating to drug samples.	100,000	1988	97.869	97,869	197,869
333(f)(1)(A)		Penalty for any person who violates a requirement related to devices for each such violation.	15,000	1990	78.156	11,723	26,723
		Penalty for aggregate of all violations related to devices in a single proceeding.	1,000,000	1990	78.156	781,560	1,781,560
333(f)(2)(A)		Penalty for any individual who introduces or delivers for introduction into interstate commerce food that is adulterated per 21 U.S.C. 342(a)(2)(B) or any individual who does not comply with a recall order under 21 U.S.C. 350l.	50,000	1996	50.425	25,123	75,123
		Penalty in the case of any other person other than an individual for such introduction or delivery of adulterated food.	250,000	1996	50.425	125,613	375,613
		Penalty for aggregate of all such violations related to adulterated food adjudicated in a single proceeding.	500,000	1996	50.425	251,225	751,225
333(f)(3)(A)		Penalty for all violations adjudicated in a single proceeding for any person who fails to submit certification required by 42 U.S.C. 282(j)(5)(B) or knowingly submitting a false certification.	10,000	2007	13.833	1,383	11,383
333(f)(3)(B)		Penalty for each day the above violation is not corrected after a 30-day period following notification until the violation is corrected.	10,000	2007	13.833	1,383	11,383

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[2] Based upon the Consumer Price Index (CPI–U) for the month of October 2015. The CPI–U is published by the Department of Labor, Bureau of Labor Statistics, and is available at its Web site: *http://www.bls.gov/cpi/*.

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description[2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment[3]	Percentage increase[4]	Increase ($)[5]	Maximum adjusted penalty ($)
U.S.C.	CFR[1]						
333(f)(4)(A)(i)		Penalty for any responsible person that violates a requirement of 21 U.S.C. 355(o) (post-marketing studies, clinical trials, labeling), 21 U.S.C. 355(p) (risk evaluation and mitigation (REMS)), or 21 U.S.C. 355–1 (REMS).	250,000	2007	13.833	34,583	284,583
		Penalty for aggregate of all such above violations in a single proceeding.	1,000,000	2007	13.833	138,330	1,138,330
333(f)(4)(A)(ii)		Penalty for REMS violation that continues after written notice to the responsible person for the first 30-day period (or any portion thereof) the responsible person continues to be in violation.	250,000	2007	13.833	34,583	284,583
		Penalty for REMS violation that continues after written notice to responsible person doubles for every 30-day period thereafter the violation continues, but may not exceed penalty amount for any 30-day period.	1,000,000	2007	13.833	138,330	1,138,330
		Penalty for aggregate of all such above violations adjudicated in a single proceeding.	10,000,000	2007	13.833	1,383,300	11,383,300
333(f)(9)(A)		Penalty for any person who violates a requirement which relates to tobacco products for each such violation.	15,000	2009	10.02	1,503	16,503
		Penalty for aggregate of all such violations of tobacco product requirement adjudicated in a single proceeding.	1,000,000	2009	10.02	100,200	1,100,200
333(f)(9)(B)(i)(I)		Penalty per violation related to violations of tobacco requirements.	250,000	2009	10.02	25,050	275,050
		Penalty for aggregate of all such violations of tobacco product requirements adjudicated in a single proceeding.	1,000,000	2009	10.02	100,200	1,100,200
333(f)(9)(B)(i)(II)		Penalty in the case of a violation of tobacco product requirements that continues after written notice to such person, for the first 30-day period (or any portion thereof) the person continues to be in violation.	250,000	2009	10.02	25,050	275,050
		Penalty for violation of tobacco product requirements that continues after written notice to such person shall double for every 30-day period thereafter the violation continues, but may not exceed penalty amount for any 30-day period.	1,000,000	2009	10.02	100,200	1,100,200
		Penalty for aggregate of all such violations related to tobacco product requirements adjudicated in a single proceeding.	10,000,000	2009	10.02	1,002,000	11,002,000
333(f)(9)(B)(ii)(I)		Penalty for any person who either does not conduct post-market surveillance and studies to determine impact of a modified risk tobacco product for which the HHS Secretary has provided them an order to sell, or who does not submit a protocol to the HHS Secretary after being notified of a requirement to conduct post-market surveillance of such tobacco products.	250,000	2009	10.02	25,050	275,050
		Penalty for aggregate of for all such above violations adjudicated in a single proceeding.	1,000,000	2009	10.02	100,200	1,100,200

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description[2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment[3]	Percentage increase[4]	Increase ($)[5]	Maximum adjusted penalty ($)
U.S.C.	CFR[1]						
333(f)(9)(B)(ii)(II)		Penalty for violation of modified risk tobacco product post-market surveillance that continues after written notice to such person for the first 30-day period (or any portion thereof) that the person continues to be in violation.	250,000	2009	10.02	25,050	275,050
		Penalty for post-notice violation of modified risk tobacco product post-market surveillance shall double for every 30-day period thereafter that the tobacco product requirement violation continues for any 30-day period, but may not exceed penalty amount for any 30-day period.	1,000,000	2009	10.02	100,200	1,100,200
		Penalty for aggregate above tobacco product requirement violations adjudicated in a single proceeding.	10,000,000	2009	10.02	1,002,000	11,002,000
333(g)(1)		Penalty for any person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading for the first such violation in any 3-year period.	250,000	2007	13.833	34,583	284,583
		Penalty for each subsequent above violation in any 3-year period.	500,000	2007	13.833	69165	569,165
333 note		Penalty to be applied for violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (*e.g.,* violations of regulations in 21 CFR Part 1140) with respect to a retailer with an approved training program in the case of a second regulation violation within a 12-month period.	250	2009	10.02	25	275
		Penalty in the case of a third tobacco product regulation violation within a 24-month period.	500	2009	10.02	50	550
		Penalty in the case of a fourth tobacco product regulation violation within a 24-month period.	2,000	2009	10.02	200	2,200
		Penalty in the case of a fifth tobacco product regulation violation within a 36-month period.	5,000	2009	10.02	501	5,501
		Penalty in the case of a sixth or subsequent tobacco product regulation violation within a 48-month period as determined on a case-by-case basis.	10,000	2009	10.02	1,002	11,002
		Penalty to be applied for violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (*e.g.,* violations of regulations in 21 CFR Part 1140) with respect to a retailer that does not have an approved training program in the case of the first regulation violation.	250	2009	10.02	25	275
		Penalty in the case of a second tobacco product regulation violation within a 12-month period.	500	2009	10.02	50	550
		Penalty in the case of a third tobacco product regulation violation within a 24-month period.	1,000	2009	10.02	100	1,100
		Penalty in the case of a fourth tobacco product regulation violation within a 24-month period.	2,000	2009	10.02	200	2,200
		Penalty in the case of a fifth tobacco product regulation violation within a 36-month period.	5,000	2009	10.02	501	5,501

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description[2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment[3]	Percentage increase[4]	Increase ($)[5]	Maximum adjusted penalty ($)
U.S.C.	CFR[1]						
		Penalty in the case of a sixth or subsequent tobacco product regulation violation within a 48-month period as determined on a case-by-case basis.	10,000	2009	10.02	1002	11,002
335b(a)	....	Penalty for each violation for any individual who made a false statement or misrepresentation of a material fact, bribed, destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document, failed to disclose a material fact, obstructed an investigation, employed a consultant who was debarred, debarred individual provided consultant services.	250,000	1992	67.728	169,320	419,320
		Penalty in the case of any other person (other than an individual) per above violation.	1,000,000	1992	67.728	677,280	1,677,280
360pp(b)(1)	....	Penalty for any person who violates any such requirements for electronic products, with each unlawful act or omission constituting a separate violation.	1,100	1968	150	1,500	2,750
		Penalty imposed for any related series of violations of requirements relating to electronic products.	375,000	1968	150	562,500	937,500
42 U.S.C. (FDA):							
262(d)	....	Penalty per day for violation of order of recall of biological product presenting imminent or substantial hazard.	100,000	1986	115.628	115,628	215,628
263b(h)(3)	....	Penalty for failure to obtain a mammography certificate as required.	10,000	1992	67.728	6,773	16,773
300aa–28(b)(1)	....	Penalty per occurrence for any vaccine manufacturer that intentionally destroys, alters, falsifies, or conceals any record or report required.	100,000	1986	115.628	115,628	215,628
42 U.S.C. (HRSA):							
256b(d)(1)(B)(vi)	....	Penalty for each instance of overcharging a 340B covered entity.	5,000	2010	8.745	437	5,437
42 U.S.C. (AHRQ):							
299c–(3)(d)	....	Penalty for an establishment or person supplying information obtained in the course of activities for any purpose other than the purpose for which it was supplied.	10,000	1999	41.402	4,140	14,140
42 U.S.C. ACF:							
653(l)(2)	45 CFR 303.21(f)	Penalty for Misuse of Information in the National Directory of New Hires.	1,000	1998	45.023	450	1,450
42 U.S.C. (OIG):							
262a(i)(1)	42 CFR Part 1003	Penalty for each individual who violates safety and security procedures related to handling dangerous biological agents and toxins.	250,000	2002	31.185	77,962	327,962
		Penalty for any other person who violates safety and security procedures related to handling dangerous biological agents and toxins.	500,000	2002	31.185	155,925	655,925
1320a–7a(a)	42 CFR Part 1003	Penalty for knowingly presenting or causing to be presented to an officer, employee, or agent of the United States a false claim.	10,000	1996	50.245	5,024	15,024
		Penalty for knowingly presenting or causing to be presented a request for payment which violates the terms of an assignment, agreement, or PPS agreement.	10,000	1996	50.245	5,024	15,024

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description [2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment [3]	Percentage increase [4]	Increase ($) [5]	Maximum adjusted penalty ($)
U.S.C.	CFR [1]						
		Penalty for knowingly giving or causing to be presented to a participating provider or supplier false or misleading information that could reasonably be expected to influence a discharge decision.	15,000	1996	50.245	7,537	22,537
		Penalty for an excluded party retaining ownership or control interest in a participating entity.	10,000	1996	50.245	5,024	15,024
		Penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.	10,000	1996	50.245	5,024	15,024
		Penalty for employing or contracting with an excluded individual.	10,000	1997	47.177	4,718	14,718
		Penalty for knowing and willful solicitation, receipt, offer, or payment of remuneration for referring an individual for a service or for purchasing, leasing, or ordering an item to be paid for by a Federal health care program.	50,000	1997	47.177	23,588	73,588
		Penalty for ordering or prescribing medical or other item or service during a period in which the person was excluded.	10,000	2010	8.745	874	10,874
		Penalty for knowingly making or causing to be made a false statement, omission or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider or supplier.	50,000	2010	8.745	4,372	54,372
		Penalty for knowing of an overpayment and failing to report and return.	10,000	2010	8.745	874	10,874
		Penalty for making or using a false record or statement that is material to a false or fraudulent claim.	50,000	2010	8.745	4,372	54,372
		Penalty for failure to grant timely access to HHS OIG for audits, investigations, evaluations, and other statutory functions of HHS OIG.	15,000	2010	8.745	1,312	16,312
1320a–7a(b)	42 CFR Part 1003	Penalty for payments by a hospital or critical access hospital to induce a physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	2,000	1986	115.628	2,313	4,313
		Penalty for physicians who knowingly receive payments from a hospital or critical access hospital to induce such physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	2,000	1986	115.628	2,313	4,313
		Penalty for a physician who executes a document that falsely certifies home health needs for Medicare beneficiaries.	5,000	1996	50.245	2,512	7,512
1320a–7e(b)(6)(A)	42 CFR Part 1003	Penalty for failure to report any final adverse action taken against a health care provider, supplier, or practitioner.	25,000	1997	47.177	11,794	36,794
1320b–10(b)(1)	42 CFR Part 1003	Penalty for the misuse of words, symbols, or emblems in communications in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS.	5,000	1988	97.869	4,893	9,893

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description [2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment [3]	Percentage increase [4]	Increase ($) [5]	Maximum adjusted penalty ($)
U.S.C.	CFR [1]						
1320b–10(b)(2)	42 CFR Part 1003	Penalty for the misuse of words, symbols, or emblems in a broadcast or telecast in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS.	25,000	1988	97.869	24,467	49,467
1395i–3(b)(3)(B)(ii)(1)		Penalty for certification of a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	1,000	1987	106.278	1,063	2,063
1395i–3(b)(3)(B)(ii)(2)		Penalty for causing another to certify or make a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	5,000	1987	106.278	5,314	10,314
1395i–3(g)(2)(A)		Penalty for any individual who notifies or causes to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted.	2,000	1987	106.278	2,126	4,126
1395w–27(g)(2)(A)	42 CFR 422.752; 42 CFR Part 1003.	Penalty for a Medicare Advantage organization that substantially fails to provide medically necessary, required items and services.	25,000	1996	50.245	12,561	37,561
		Penalty for a Medicare Advantage organization that charges excessive premiums.	25,000	1997	47.177	11,794	36,794
		Penalty for a Medicare Advantage organization that improperly expels or refuses to reenroll a beneficiary.	25,000	1997	47.177	11,794	36,794
		Penalty for a Medicare Advantage organization that engages in practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	100,000	1997	47.177	47,177	147,177
		Penalty per individual who does not enroll as a result of a Medicare Advantage organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	15,000	1997	47.177	7,077	22,077
		Penalty for a Medicare Advantage organization misrepresenting or falsifying information to Secretary.	100,000	1997	47.177	47,177	147,177
		Penalty for a Medicare Advantage organization misrepresenting or falsifying information to individual or other entity.	25,000	1997	47.177	11,794	36,794
		Penalty for Medicare Advantage organization interfering with provider's advice to enrollee and non-MCO affiliated providers that balance bill enrollees.	25,000	1997	47.177	11,794	36,794
		Penalty for a Medicare Advantage organization that employs or contracts with excluded individual or entity.	25,000	1997	47.177	11,794	36,794
		Penalty for a Medicare Advantage organization enrolling an individual in without prior written consent.	25,000	2010	47.177	11,794	36,794
		Penalty for a Medicare Advantage organization transferring an enrollee to another plan without consent or solely for the purpose of earning a commission.	25,000	2010	47.177	11,794	36,794
		Penalty for a Medicare Advantage organization failing to comply with marketing restrictions or applicable implementing regulations or guidance.	25,000	2010	47.177	11,794	36,794

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description [2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment [3]	Percentage increase [4]	Increase ($) [5]	Maximum adjusted penalty ($)
U.S.C.	CFR [1]						
		Penalty for a Medicare Advantage organization employing or contracting with an individual or entity who violates 1395w–27(g)(1)(A)–(J).	25,000	2010	47.177	11,794	36,794
1395w–141(i)(3)	42 CFR Part 1003	Penalty for a prescription drug card sponsor that falsifies or misrepresents marketing materials, overcharges program enrollees, or misuse transitional assistance funds.	10,000	2003	28.561	2,856	12,856
1395cc(g)	42 CFR Part 1003	Penalty for improper billing by Hospitals, Critical Access Hospitals, or Skilled Nursing Facilities.	2,000	1972	150	3,000	5,000
1395dd(d)(1)	42 CFR Part 1003	Penalty for a hospital or responsible physician dumping patients needing emergency medical care, if the hospital has 100 beds or more.	50,000	1987	106.278	53,139	103,139
		Penalty for a hospital or responsible physician dumping patients needing emergency care, if the hospital has less than 100 beds.	25,000	1987	106.278	26,570	51,570
1395mm(i)(6)(B)(i)	42 CFR Part 1003	Penalty for a HMO or competitive plan is such plan substantially fails to provide medically necessary, required items or services.	25,000	1987	106.278	26,570	51,570
		Penalty for HMOs/competitive medical plans that charge premiums in excess of permitted amounts.	25,000	1987	106.278	26,570	51,570
		Penalty for a HMO or competitive medical plan that expels or refuses to reenroll an individual per prescribed conditions.	25,000	1987	106.278	26,570	51,570
		Penalty for a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in future.	100,000	1987	106.278	106,278	206,278
		Penalty per individual not enrolled in a plan as a result of a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in the future.	15,000	1988	97.869	14,680	29,680
		Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to the Secretary.	100,000	1987	106.278	106,278	206,278
		Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to an individual or any other entity.	25,000	1987	106.278	26,570	51,570
		Penalty for failure by HMO or competitive medical plan to assure prompt payment of Medicare risk sharing contracts or incentive plan provisions.	25,000	1987	106.278	26,570	51,570
		Penalty for HMO that employs or contracts with excluded individual or entity.	25,000	1989	89.361	22,340	47,340
1395nn(g)(3)	42 CFR Part 1003	Penalty for submitting or causing to be submitted claims in violation of the Stark Law's restrictions on physician self-referrals.	15,000	1994	59.089	8,863	23,863
1395nn(g)(4)	42 CFR Part 1003	Penalty for circumventing Stark Law's restrictions on physician self-referrals.	100,000	1994	59.089	59,089	159,089
1395ss(d)(1)	42 CFR Part 1003	Penalty for a material misrepresentation regarding Medigap compliance policies.	5,000	1988	97.869	4,893	9,893
1395ss(d)(2)	42 CFR Part 1003	Penalty for selling Medigap policy under false pretense.	5,000	1988	97.869	4,893	9,893
1395ss(d)(3)(A)(ii)	42 CFR Part 1003	Penalty for an issuer that sells health insurance policy that duplicates benefits.	25,000	1990	78.156	19,539	44,539

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description [2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment [3]	Percentage increase [4]	Increase ($) [5]	Maximum adjusted penalty ($)
U.S.C.	CFR [1]						
		Penalty for someone other than issuer that sells health insurance that duplicates benefits.	15,000	1990	78.156	11,723	26,723
1395ss(d)(4)(A)	42 CFR Part 1003	Penalty for using mail to sell a non-approved Medigap insurance policy.	5,000	1988	97.869	4,893	9,893
1396b(m)(5)(B)(i)	42 CFR Part 1003	Penalty for a Medicaid MCO that substantially fails to provide medically necessary, required items or services.	25,000	1988	97.869	24,467	49,467
		Penalty for a Medicaid MCO that charges excessive premiums.	25,000	1988	97.869	24,467	49,467
		Penalty for a Medicaid MCO that improperly expels or refuses to reenroll a beneficiary.	100,000	1988	97.869	97,869	197,869
		Penalty per individual who does not enroll as a result of a Medicaid MCO's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	15,000	1988	97.869	14,680	29,680
		Penalty for a Medicaid MCO misrepresenting or falsifying information to the Secretary.	100,000	1988	97.869	97,869	197,869
		Penalty for a Medicaid MCO misrepresenting or falsifying information to an individual or another entity.	25,000	1988	97.869	24,467	49,467
		Penalty for a Medicaid MCO that fails to comply with contract requirements with respect to physician incentive plans.	25,000	1990	78.156	19,539	44,539
1396r(b)(3)(B)(ii)(I)	42 CFR Part 1003	Penalty for willfully and knowingly certifying a material and false statement in a Skilled Nursing Facility resident assessment.	1,000	1987	106.278	1,063	2,063
1396r(b)(3)(B)(ii)(II)	42 CFR Part 1003	Penalty for willfully and knowingly causing another individual to certify a material and false statement in a Skilled Nursing Facility resident assessment.	5,000	1987	106.278	5,314	10,314
1396r(g)(2)(A)(i)	42 CFR Part 1003	Penalty for notifying or causing to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted.	2,000	1987	106.278	2,126	4,126
1396r–8(b)(3)(B)	42 CFR Part 1003	Penalty for the knowing provision of false information or refusing to provide information about charges or prices of a covered outpatient drug.	100,000	1990	78.156	78,156	178,156
1396r–8(b)(3)(C)(i)	42 CFR Part 1003	Penalty per day for failure to timely provide information by drug manufacturer with rebate agreement.	10,000	1990	78.156	7,816	17,816
1396r–8(b)(3)(C)(ii)	42 CFR Part 1003	Penalty for knowing provision of false information by drug manufacturer with rebate agreement.	100,000	1990	78.156	78,156	178,156
1396t(i)(3)(A)	42 CFR Part 1003	Penalty for notifying home and community-based providers or settings of survey.	2,000	1990	78.156	1,563	3,563
11131(c)	42 CFR Part 1003	Penalty for failing to report a medical malpractice claim to National Practitioner Data Bank.	10,000	1986	115.628	11,563	21,563
11137(b)(2)	42 CFR Part 1003	Penalty for breaching confidentiality of information reported to National Practitioner Data Bank.	10,000	1986	115.628	11,563	21,563
42 U.S.C. (OCR):							
299b–22(f)(1)	42 CFR 3.404(b)	Penalty for violation of confidentiality provision of the Patient Safety and Quality Improvement Act.	10,000	2005	19.40	1,940	11,940
1320(d)–5(a)	45 CFR 160.404(b)(1)(i),(ii).	Penalty for each pre-February 18, 2009 violation of the HIPAA administrative simplification provisions.	100	1996	50.245	50	150
		Calendar Year Cap	25,000	1996	50.245	12,561	37,561

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description[2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment[3]	Percentage increase[4]	Increase ($)[5]	Maximum adjusted penalty ($)
U.S.C.	CFR[1]						
	45 CFR 160.404(b)(2)(i)(A),(B).	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the covered entity or business associate did not know and by exercising reasonable diligence, would not have known that the covered entity or business associate violated such a provision:					
		Minimum	100	2009	10.02	10	110
		Maximum	50,000	2009	10.02	5,010	55,010
		Calendar Year Cap	1,500,000	2009	10.02	150,300	1,650,300
	45 CFR 160.404(b)(2)(ii)(A), (B).	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to reasonable cause and not to willful neglect:					
		Minimum	1,000	2009	10.02	100	1100
		Maximum	50,000	2009	10.02	5,010	55,010
		Calendar Year Cap	1,500,000	2009	10.02	150,300	1,650,300
	45 CFR 160.404(b)(2)(iii)(A), (B).	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to willful neglect and was corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or, by exercising reasonable diligence, would have known that the violation occurred:					
		Minimum	10,000	2009	10.02	100	11,002
		Maximum	50,000	2009	10.02	5,010	55,010
		Calendar Year Cap	1,500,000	2009	10.02	150,300	1,650,300
	45 CFR 160.404(b)(2)(iv)(A), (B).	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or by exercising reasonable diligence, would have known that the violation occurred:					
		Minimum	50,000	2009	10.02	5,010	55,010
		Maximum	1,500,000	2009	10.02	150,300	1,650,300
		Calendar Year Cap	1,500,000	2009	10.02	150,300	1,650,300
42 U.S.C. (CMS):							
263a(h)(2)(B) & 1395w–2(b)(2)(A)(ii).	42 CFR 493.1834(d)(2)(i).	Penalty for a clinical laboratory's failure to meet participation and certification requirements and poses immediate jeopardy:					
		Minimum	3,050	1988	97.869	2,985	6,035
		Maximum	10,000	1988	97.869	9,787	19,787
	42 CFR 493.1834(d)(2)(ii).	Penalty for a clinical laboratory's failure to meet participation and certification requirements and the failure does not pose immediate jeopardy:					
		Minimum	50	1988	97.869	49	99
		Maximum	3,000	1988	97.869	2,936	5,936
300gg–15(f)	45 CFR 147.200(e)	Failure to provide the Summary of Benefits and Coverage (SBC).	1,000	2010	8.745	87	1,087
300gg–18	45 CFR 158.606	Penalty for violations of regulations related to the medical loss ratio reporting and rebating.	100	2010	8.745	9	109

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description[2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment[3]	Percentage increase[4]	Increase ($)[5]	Maximum adjusted penalty ($)
U.S.C.	CFR[1]						
1320a–7h(b)(1)	42 CFR 402.105(d)(5), 42 CFR 403.912(a) & (c).	Penalty for manufacturer or group purchasing organization failing to report information required under 42 U.S.C. 1320a–7h(a), relating to physician ownership or investment interests:					
		Minimum	1,000	2010	8.745	87	1,087
		Maximum	10,000	2010	8.745	874	10,874
		Calendar Year Cap	150,000	2010	8.745	13,117	163,117
1320a–7h(b)(2)	42 CFR 402.105(h), 42 CFR 403 912(b) & (c).	Penalty for manufacturer or group purchasing organization knowingly failing to report information required under 42 U.S.C. 1320a–7h(a) , relating to physician ownership or investment interests:					
		Minimum	10,000	2010	8.745	874	10,874
		Maximum	100,000	2010	8.745	8,745	108,745
		Calendar Year Cap	1,000,000	2010	8.745	87,450	1,087,450
1320a–7j(h)(3)(A)	....	Penalty for an administrator of a facility that fails to comply with notice requirements for the closure of a facility.	100,000	2010	8.745	8,745	108,745
	42 CFR 488.446(a)(1),(2), & (3).	Minimum penalty for the first offense of an administrator who fails to provide notice of facility closure.	500	2010	8.745	44	544
		Minimum penalty for the second offense of an administrator who fails to provide notice of facility closure.	1,500	2010	8.745	131	1,631
		Minimum penalty for the third and subsequent offenses of an administrator who fails to provide notice of facility closure.	3,000	2010	8.745	262	3,262
1320a–8(a)(1)	....	Penalty for an entity knowingly making a false statement or representation of material fact in the determination of the amount of benefits or payments related to old-age, survivors, and disability insurance benefits, special benefits for certain World War II veterans, or supplemental security income for the aged, blind, and disabled.	5,000	1994	59.089	2,954	7,954
		Penalty for the violation of 42 U.S.C. 1320a–8a(1) if the violator is a person who receives a fee or other income for services performed in connection with determination of the benefit amount or the person is a physician or other health care provider who submits evidence in connection with such a determination.	7,500	2015	1	4,431	7,500
1320a–8(a)(3)	....	Penalty for a representative payee (under 42 U.S.C. 405(j), 1007, or 1383(a)(2)) converting any part of a received payment from the benefit programs described in the previous civil monetary penalty to a use other than for the benefit of the beneficiary.	5,000	2004	24.588	1,229	6,229
1320b–25(c)(1)(A)	....	Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility.	200,000	2010	8.745	17,490	217,490

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description [2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment [3]	Percentage increase [4]	Increase ($) [5]	Maximum adjusted penalty ($)
U.S.C.	CFR [1]						
1320b–25(c)(2)(A)		Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility if such failure exacerbates the harm to the victim of the crime or results in the harm to another individual.	300,000	2010	8.745	26,235	326,235
1320b–25(d)(2)		Penalty for a long-term care facility that retaliates against any employee because of lawful acts done by the employee, or files a complaint or report with the State professional disciplinary agency against an employee or nurse for lawful acts done by the employee or nurse.	200,000	2010	8.745	17,490	217,490
1395b–7(b)(2)(B)	42 CFR 402.105(g)	Penalty for any person who knowingly and willfully fails to furnish a beneficiary with an itemized statement of items or services within 30 days of the beneficiary's request.	100	1997	47.177	47	147
1395i–3(h)(2)(B)(ii)(I)	42 CFR 488.408(d)(1)(iii)	Penalty per day for a Skilled Nursing Facility that has a Category 2 violation of certification requirements:					
		Minimum	50	1987	106.278	53	103
		Maximum	3,000	1987	106.278	3,188	6,188
	42 CFR 488.408(d)(1)(iv).	Penalty per instance of Category 2 noncompliance by a Skilled Nursing Facility:					
		Minimum	1,000	1987	106.278	1,063	2,063
		Maximum	10,000	1987	106.278	10,628	20,628
	42 CFR 488.408(e)(1)(iii)	Penalty per day for a Skilled Nursing Facility that has a Category 3 violation of certification requirements:					
		Minimum	3,050	1987	106.278	3,241	6,291
		Maximum	10,000	1987	106.278	10,628	20,628
	42 CFR 488.408(e)(1)(iv).	Penalty per instance of Category 3 noncompliance by a Skilled Nursing Facility:					
		Minimum	1,000	1987	106.278	1,063	2,063
		Maximum	10,000	1987	106.278	10,628	20,628
		Penalty per day and per instance for a Skilled Nursing Facility that has Category 3 noncompliance with Immediate Jeopardy.					
		Per Day (Minimum)	3,050	1987	106.278	3,241	6,291
		Per Day (Maximum)	10,000	1987	106.278	10,628	20,628
		Per Instance (Minimum)	1,000	1987	106.278	1,063	2,063
		Per Instance (Maximum)	10,000	1987	106.278	10,628	20,628
	42 CFR 488.438(a)(1)(i)	Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the upper range per day:					
		Minimum	3,050	1987	106.278	3,241	6,291
		Maximum	10,000	1987	106.278	10,628	20,628
	42 CFR 488.438(a)(1)(ii)	Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the lower range per day:					
		Minimum	50	1987	106.278	53	103
		Maximum	3,000	1987	106.278	3,188	6,188
	42 CFR 488.438(a)(2)	Penalty per instance of a Skilled Nursing Facility that fails to meet certification requirements:					
		Minimum	1,000	1987	106.278	1,063	2,063
		Maximum	10,000	1987	106.278	10,628	20,628

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description [2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment [3]	Percentage increase [4]	Increase ($) [5]	Maximum adjusted penalty ($)
U.S.C.	CFR [1]						
1395l(h)(5)(D)	42 CFR 402.105(d)(2)(i)	Penalty for knowingly, willfully, and repeatedly billing for a clinical diagnostic laboratory test other than on an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395l(i)(6)	....	Penalty for knowingly and willfully presenting or causing to be presented a bill or request for payment for an intraocular lens inserted during or after cataract surgery for which the Medicare payment rate includes the cost of acquiring the class of lens involved.	2,000	1988	197.869	1,957	3,957
1395l(q)(2)(B)(i)	42 CFR 402.105(a)	Penalty for knowingly and willfully failing to provide information about a referring physician when seeking payment on an unassigned basis.	2,000	1989	89.361	1,787	3,787
1395m(a)(11)(A)	42 CFR 402.1(c)(4), 402.105(d)(2)(ii).	Penalty for any durable medical equipment supplier that knowingly and willfully charges for a covered service that is furnished on a rental basis after the rental payments may no longer be made. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395m(a)(18)(B)	42 CFR 402.1(c)(5), 402.105(d)(2)(iii).	Penalty for any nonparticipating durable medical equipment supplier that knowingly and willfully fails to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395m(b)(5)(C)	42 CFR 402.1(c)(6), 402.105(d)(2)(iv).	Penalty for any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge for radiologist services. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395m(h)(3)	42 CFR 402.1(c)(8), 402.105(d)(2)(vi).	Penalty for any supplier of prosthetic devices, orthotics, and prosthetics that knowing and willfully charges for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(a)(11)(A), that is in the same manner as 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description [2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment [3]	Percentage increase [4]	Increase ($) [5]	Maximum adjusted penalty ($)
U.S.C.	CFR [1]						
1395m(j)(2)(A)(iii)		Penalty for any supplier of durable medical equipment including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully distributes a certificate of medical necessity in violation of Section 1834(j)(2)(A)(i) of the Act or fails to provide the information required under Section 1834(j)(2)(A)(ii) of the Act.	1,000	1994	59.089	591	1,591
1395m(j)(4)	42 CFR 402.1(c)(10), 402.105(d)(2)(vii).	Penalty for any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for series billed other than on as assignment-related basis under certain conditions. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(j)(4) and 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395m(k)(6)	42 CFR 402.1(c)(31), 402.105(d)(3).	Penalty for any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(k)(6) and 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395m(l)(6)	42 CFR 402.1(c)(32), 402.105(d)(4).	Penalty for any supplier of ambulance services who knowingly and willfully fills or collects for any services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(b)(18)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395u(b)(18)(B)	42 CFR 402.1(c)(11), 402.105(d)(2)(viii).	Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395u(j)(2)(B)	42 CFR 402.1(c)	Penalty for any physician who charges more than 125% for a non-participating referral. (Penalties are assessed in the same manner as 42 U.S.C. 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395u(k)	42 CFR 402.1(c)(12), 402.105(d)(2)(ix).	Penalty for any physician who knowingly and willfully presents or causes to be presented a claim for bill for an assistant at a cataract surgery performed on or after March 1, 1987, for which payment may not be made because of section 1862(a)(15). (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description [2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment [3]	Percentage increase [4]	Increase ($) [5]	Maximum adjusted penalty ($)
U.S.C.	CFR [1]						
1395u(l)(3)	42 CFR 402.1(c)(13), 402.105(d)(2)(x).	Penalty for any nonparticipating physician who does not accept payment on an assignment-related basis and who knowingly and willfully fails to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality under 1842(l)(1)(A). (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395u(m)(3)	42 CFR 402.1(c)(14), 402.105(d)(2)(xi).	Penalty for any nonparticipating physician charging more than $500 who does not accept payment for an elective surgical procedure on an assignment related basis and who knowingly and willfully fails to disclose the required information regarding charges and coinsurance amounts and fails to refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395u(n)(3)	42 CFR 402.1(c)(15), 402.105(d)(2)(xii).	Penalty for any physician who knowingly, willfully, and repeatedly bills one or more beneficiaries for purchased diagnostic tests any amount other than the payment amount specified by the Act. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395u(o)(3)(B)	42 CFR 414.707(b)	Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services pertaining to drugs or biologics by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(b)(18)(B) and 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395u(p)(3)(A)		Penalty for any physician or practitioner who knowingly and willfully fails promptly to provide the appropriate diagnosis codes upon CMS or Medicare administrative contractor request for payment or bill not submitted on an assignment-related basis.	2,000	1988	97.869	1,957	3,957
1395w–3a(d)(4)(A)	42 CFR 414.806	Penalty for a pharmaceutical manufacturer's misrepresentation of average sales price of a drug, or biologic.	10,000	2003	28.561	2,856	12,856

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description[2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment[3]	Percentage increase[4]	Increase ($)[5]	Maximum adjusted penalty ($)
U.S.C.	CFR[1]						
1395w–4(g)(1)(B)	42 CFR 402.1(c)(17), 402.105(d)(2)(xiii).	Penalty for any nonparticipating physician, supplier, or other person that furnishes physician services not on an assignment-related basis who either knowingly and willfully bills or collects in excess of the statutorily-defined limiting charge or fails to make a timely refund or adjustment. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395w–4(g)(3)(B)	42 CFR 402.1(c)(18), 402.105(d)(2)(xiv).	Penalty for any person that knowingly and willfully bills for statutorily defined State-plan approved physicians' services on any other basis than an assignment-related basis for a Medicare/Medicaid dual eligible beneficiary. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395w–27(g)(3)(A); 1857(g)(3).	42 CFR 422.760(b); 42 CFR 423.760(b).	Penalty for each termination determination the Secretary makes that is the result of actions by a Medicare Advantage organization or Part D sponsor that has adversely affected an individual covered under the organization's contract.	25,000	1997	47.177	11,794	36,794
1395w–27(g)(3)(B); 1857(g)(3).	....	Penalty for each week beginning after the initiation of civil money penalty procedures by the Secretary because a Medicare Advantage organization or Part D sponsor has failed to carry out a contract, or has carried out a contract inconsistently with regulations.	10,000	1997	47.177	4,718	14,718
1395w–27(g)(3)(D); 1857(g)(3).	....	Penalty for a Medicare Advantage organization's or Part D sponsor's early termination of its contract.	100,000	2000	36.689	36,689	136,689
1395y(b)(3)(C)	42 CFR 411.103(b)	Penalty for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits not to enroll under a group health plan or large group health plan which would be a primary plan.	5,000	1990	78.156	3,908	8,908
1395y(b)(5)(C)(ii)	42 CFR 402.1(c)(20), 402.105(b)(2).	Penalty for any non-governmental employer that, before October 1, 1998, willfully or repeatedly failed to provide timely and accurate information requested relating to an employee's group health insurance coverage.	1,000	1998	89.361	450	1,450
1395y(b)(6)(B)	42 CFR 402.1(c)(21), 402.105(a).	Penalty for any entity that knowingly, willfully, and repeatedly fails to complete a claim form relating to the availability of other health benefits in accordance with statute or provides inaccurate information relating to such on the claim form.	2,000	1994	59.089	1,182	3,182
1395y(b)(7)(B)(i)	....	Penalty for any entity serving as insurer, third party administrator, or fiduciary for a group health plan that fails to provide information that identifies situations where the group health plan is or was a primary plan to Medicare to the HHS Secretary.	1,000	2007	13.833	138	1,138

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description [2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment [3]	Percentage increase [4]	Increase ($) [5]	Maximum adjusted penalty ($)
U.S.C.	CFR [1]						
1395y(b)(8)(E)		Penalty for any non-group health plan that fails to identify claimants who are Medicare beneficiaries and provide information to the HHS Secretary to coordinate benefits and pursue any applicable recovery claim.	1,000	2007	13.833	138	1,138
1395nn(g)(5)	42 CFR 411.361	Penalty for any person that fails to report information required by HHS under Section 1877(f) concerning ownership, investment, and compensation arrangements.	10,000	1989	89.361	8,936	18,936
1395pp(h)	42 CFR 402.1(c)(23), 402.105(d)(2)(xv).	Penalty for any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries under certain conditions. (42 U.S.C. 1395(m)(18) sanctions apply here in the same manner, which is under 1395u(j)(2) and 1320a–7a(a)).	10,000	1996	50.245	5,024	15,024
1395ss(a)(2)	42 CFR 402.1(c)(24), 405.105(f)(1).	Penalty for any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards after a statutorily defined effective date.	25,000	1987	106.278	26,569	51,569
1395ss(d)(3)(A)(vi)(II).		Penalty for someone other than issuer that sells or issues a Medicare supplemental policy to beneficiary without a disclosure statement.	15,000	1990	78.156	11,723	26,723
		Penalty for an issuer that sells or issues a Medicare supplemental policy without disclosure statement.	25,000	1990	78.156	19,539	44,539
1395ss(d)(3)(B)(iv)		Penalty for someone other than issuer that sells or issues a Medicare supplemental policy without acknowledgement form.	15,000	1990	78.156	11,723	26,723
		Penalty for issuer that sells or issues a Medicare supplemental policy without an acknowledgement form.	25,000	1990	78.156	19,539	44,539
1395ss(p)(8)	42 CFR 402.1(c)(25), 402.105(e).	Penalty for any person that sells or issues Medicare supplemental polices after a given date that fail to conform to the NAIC or Federal standards established by statute.	15,000	1990	78.156	11,723	26,723
	42 CFR 402.1(c)(25), 405.105(f)(2).	Penalty for any person that sells or issues Medicare supplemental polices after a given date that fail to conform to the NAIC or Federal standards established by statute.	25,000	1990	78.156	19,539	44,539
1395ss(p)(9)(C)	42 CFR 402.1(c)(26), 402.105(e).	Penalty for any person that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	15,000	1990	78.156	11,723	26,723

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description[2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment[3]	Percentage increase[4]	Increase ($)[5]	Maximum adjusted penalty ($)
U.S.C.	CFR[1]						
	42 CFR 402.1(c)(26), 405.105(f)(3), (4).	Penalty for any person that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	25,000	1990	78.156	19,539	44,539
1395ss(q)(5)(C)	42 CFR 402.1(c)(27), 405.105(f)(5).	Penalty for any person that fails to suspend the policy of a policyholder made eligible for medical assistance or automatically reinstates the policy of a policyholder who has lost eligibility for medical assistance, under certain circumstances.	25,000	1990	78.156	19,539	44,539
1395ss(r)(6)(A)	42 CFR 402.1(c)(28), 405.105(f)(6).	Penalty for any person that fails to provide refunds or credits as required by section 1882(r)(1)(B).	25,000	1990	78.156	19,539	44,539
1395ss(s)(4)	42 CFR 402.1(c)(29), 405.105(c).	Penalty for any issuer of a Medicare supplemental policy that does not waive listed time periods if they were already satisfied under a proceeding Medicare supplemental policy, or denies a policy, or conditions the issuances or effectiveness of the policy, or discriminates in the pricing of the policy base on health status or other specified criteria.	5,000	1990	78.156	3,908	8,908
1395ss(t)(2)	42 CFR 402.1(c)(30), 405.105(f)(7).	Penalty for any issuer of a Medicare supplemental policy that fails to fulfill listed responsibilities.	25,000	1990	78.156	19,539	44,539
1395ss(v)(4)(A)	....	Penalty someone other than issuer who sells, issues, or renews a medigap Rx policy to an individual who is a Part D enrollee.	15,000	2003	28.561	4,284	19,284
		Penalty for an issuer who sells, issues, or renews a Medigap Rx policy who is a Part D enrollee.	25,000	2003	28.561	7,140	32,140
1395bbb(c)(1)	42 CFR 488.725(c)	Penalty for any individual who notifies or causes to be notified a home health agency of the time or date on which a survey of such agency is to be conducted.	2,000	1987	106.278	2,126	4,126
1395bbb(f)(2)(A)(i)	42 CFR 488.845(b)(2)(iii)	Maximum daily penalty amount for each day a home health agency is not in compliance with statutory requirements.	10,000	1988	97.869	9,787	19,787
	42 CFR 488.845(b)(3) ...	Penalty per day for home health agency's noncompliance (Upper Range):					
		Minimum	8,500	1988	97.869	8,319	16,819
		Maximum	10,000	1988	97.869	9,787	19,787
	42 CFR 488.845(b)(3)(i)	Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in actual harm.	10,000	1988	97.869	9,787	19,787
	42 CFR 488.845(b)(3)(ii)	Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in potential for harm.	9,000	1988	97.869	8,808	17,808
	42 CFR 488.845(b)(3)(iii)	Penalty for an isolated incident of noncompliance in violation of established HHA policy.	8,500	1988	97.869	8,319	16,819
	42 CFR 488.845(b)(4) ...	Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy, but is directly related to poor quality patient care outcomes (Lower Range):					
		Minimum	1,500	1988	97.869	1,468	2,968
		Maximum	8,500	1988	97.869	8,319	16,819

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description[2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment[3]	Percentage increase[4]	Increase ($)[5]	Maximum adjusted penalty ($)
U.S.C.	CFR[1]						
	42 CFR 488.845(b)(5) ...	Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy and that is related predominately to structure or process-oriented conditions (Lower Range):					
		Minimum	500	1988	97.869	489	989
		Maximum	4,000	1988	97.869	3,915	7,915
42 CFR 488.845(b)(6)	...	Penalty imposed for instance of noncompliance that may be assessed for one or more singular events of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey:					
		Minimum	1,000	1988	97.869	979	1,979
		Maximum	10,000	1988	97.869	9,787	19,787
		Penalty for each day of noncompliance (Maximum).	10,000	1988	97.869	9,787	19,787
	42 CFR 488.845(d)(1)(ii)	Penalty for each day of noncompliance (Maximum).	10,000	1988	97.869	9,787	19,787
1396b(m)(5)(B)	42 CFR 460.46	Penalty for PACE organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment:					
		Minimum	15,000	1997	47.177	7,077	22,077
		Maximum	100,000	1997	47.177	47,177	147,177
		Penalty for a PACE organization that charges excessive premiums.	25,000	1997	47.177	11,794	36,794
		Penalty for a PACE organization misrepresenting or falsifying information to CMS, the State, or an individual or other entity.	100,000	1997	47.177	47,177	147,177
		Penalty for each determination the CMS makes that the PACE organization has failed to provide medically necessary items and services of the failure has adversely affected (or has the substantial likelihood of adversely affecting) a PACE participant.	25,000	1997	47.177	11,794	36,794
		Penalty for involuntarily disenrolling a participant.	25,000	1997	47.177	11,794	36,794
		Penalty for discriminating or discouraging enrollment or disenrollment of participants on the basis of an individual's health status or need for health care services.	25,000	1997	47.177	11,794	36,794
1396r(h)(3)(C)(ii)(I) ...	42 CFR 488.408(d)(1)(iii)	Penalty per day for a nursing facility's failure to meet a Category 2 Certification:					
		Minimum	50	1987	106.278	53	103
		Maximum	3,000	1987	106.278	3,188	6,188
	42 CFR 488.408(d)(1)(iv).	Penalty per instance for a nursing facility's failure to meet Category 2 certification:					
		Minimum	1,000	1987	106.278	1,063	2,063
		Maximum	10,000	1987	106.278	10,628	20,628
	42 CFR 488.408(e)(1)(iii)	Penalty per day for a nursing facility's failure to meet Category 3 certification:					
		Minimum	3,050	1987	106.278	3,241	6,291
		Maximum	10,000	1987	106.278	10,628	20,628
	42 CFR 488.408(e)(1)(iv).	Penalty per instance for a nursing facility's failure to meet Category 3 certification:					
		Minimum	1,000	1987	106.278	1,063	2,063
		Maximum	10,000	1987	106.278	10,628	20,628
	42 CFR 488.408(e)(2)(ii)	Penalty per instance for a nursing facility's failure to meet Category 3 certification, which results in immediate jeopardy:					
		Minimum	1,000	1987	106.278	1,063	2,063
		Maximum	10,000	1987	106.278	10,628	20,628

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description[2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment[3]	Percentage increase[4]	Increase ($)[5]	Maximum adjusted penalty ($)
U.S.C.	CFR[1]						
	42 CFR 488.438(a)(1)(i)	Penalty per day for nursing facility's failure to meet certification (Upper Range):					
		Minimum	3,050	1987	106.278	3,241	6,291
		Maximum	10,000	1987	106.278	10,628	20,628
	42 CFR 488.438(a)(1)(ii)	Penalty per day for nursing facility's failure to meet certification (Lower Range):					
		Minimum	50	1987	106.278	53	103
		Maximum	3,000	1987	106.278	3,188	6,188
	42 CFR 488.438(a)(2)	Penalty per instance for nursing facility's failure to meet certification:					
		Minimum	1,000	1987	106.278	1,063	2,063
		Maximum	10,000	1987	106.278	10,628	20,628
1396r(f)(2)(B)(iii)(I)(c)	42 CFR 483.151(b)(2)(iv) and (b)(3)(iii).	Grounds to prohibit approval of Nurse Aide Training Program—if assessed a penalty in 1819(h)(2)(B)(i) or 1919(h)(2)(A)(ii) of "not less than $5,000" [Not CMP authority, but a specific CMP amount (CMP at this level) that is the triggering condition for disapproval].	5,000	1987	106.278	5,314	10,314
1396r(h)(3)(C)(ii)(I)	42 CFR 483.151(c)(2)	Grounds to waive disapproval of nurse aide training program—reference to disapproval based on imposition of CMP "not less than $5,000" [Not CMP authority but CMP imposition at this level determines eligibility to seek waiver of disapproval of nurse aide training program].	5,000	1987	106.278	5,314	10,314
1396t(j)(2)(C)		Penalty for each day of noncompliance for a home or community care provider that no longer meets the minimum requirements for home and community care:					
		Minimum	1	1990	78.156	1	2
		Maximum	10,000	1990	78.156	7,816	17,816
1396u–2(e)(2)(A)(i)	42 CFR 438.704	Penalty for a Medicaid managed care organization that fails substantially to provide medically necessary items and services.	25,000	1997	47.177	11,794	36,794
		Penalty for Medicaid managed care organization that imposes premiums or charges on enrollees in excess of the premiums or charges permitted.	25,000	1997	47.177	11,794	36,794
		Penalty for a Medicaid managed care organization that misrepresents or falsifies information to another individual or entity.	25,000	1997	47.177	11,794	36,794
		Penalty for a Medicaid managed care organization that fails to comply with the applicable statutory requirements for such organizations.	25,000	1997	47.177	11,794	36,794
1396u–2(e)(2)(A)(ii)	42 CFR 438.704	Penalty for a Medicaid managed care organization that misrepresents or falsifies information to the HHS Secretary.	100,000	1997	47.177	47,177	147,177
		Penalty for Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	100,000	1997	47.177	47,177	147,177
1396u–2(e)(2)(A)(iv)	42 CFR 438.704	Penalty for each individual that does not enroll as a result of a Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	15,000	1997	47.177	7,077	22,077
1396u(h)(2)	42 CFR 441, Subpart I	Penalty for a provider not meeting one of the requirements relating to the protection of the health, safety, and welfare of individuals receiving community supported living arrangements services.	10,000	1990	106.278	10,628	20,628

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description[2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment[3]	Percentage increase[4]	Increase ($)[5]	Maximum adjusted penalty ($)
U.S.C.	CFR[1]						
1396w–2(c)(1)		Penalty for disclosing information related to eligibility determinations for medical assistance programs.	10,000	2009	10.02	1,002	11,002
1903(m)(5)(B)	42 CFR 460.46	Penalty for PACE organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment:					
		Minimum	15,000	1997	47.177	7,077	22,077
		Maximum	100,000	1997	47.177	47,177	147,177
		Penalty for a PACE organization that charges excessive premiums.	25,000	1997	47.177	11,794	36,794
		Penalty for a PACE organization misrepresenting or falsifying information to CMS, the State, or an individual or other entity.	100,000	1997	47.177	47,177	147,177
		Penalty for each determination the CMS makes that the PACE organization has failed to provide medically necessary items and services of the failure has adversely affected (or has the substantial likelihood of adversely affecting) a PACE participant.	25,000	1997	47.177	11,794	36,794
		Penalty for involuntarily disenrolling a participant.	25,000	1997	47.177	11,794	36,794
		Penalty for discriminating or discouraging enrollment or disenrollment of participants on the basis of an individual's health status or need for health care services.	25,000	1997	47.177	11,794	36,794
18041(c)(2)	45 CFR 150.315 and 45 CFR 156.805(c).	Failure to comply with requirements of Public Health Services Act; Penalty for violations of rules or standards of behavior associated with issuer participation in the Federally-facilitated Exchange. (42 U.S.C. 300gg–22(b)(C)).	100	1996	50.245	50	150
18081(h)(1)(A)(i)(II)	42 CFR 155.285	Penalty for providing false information on Exchange application.	25,000	2010	8.745	2,186	27,186
18081(h)(1)(B)	42 CFR 155.285	Penalty for knowingly or willfully providing false information on Exchange application.	250,000	2010	8.745	21,862	271,862
18081(h)(2)	42 CFR 155.260	Penalty for knowingly or willfully disclosing protected information from Exchange.	25,000	2010	8.745	2,186	27,186
31 U.S.C. (HHS):							
1352	45 CFR 93.400(e)	Penalty for the first time an individual makes an expenditure prohibited by regulations regarding lobbying disclosure, absent aggravating circumstances.	10,000	1989	89.361	8,936	18,936
		Penalty for second and subsequent offenses by individuals who make an expenditure prohibited by regulations regarding lobbying disclosure:					
		Minimum	10,000	1989	89.361	8,936	18,936
		Maximum	100,000	1989	89.361	89,361	189,361
		Penalty for the first time an individual fails to file or amend a lobbying disclosure form, absent aggravating circumstances.	10,000	1989	89.361	8,936	18,936
		Penalty for second and subsequent offenses by individuals who fail to file or amend a lobbying disclosure form, absent aggravating circumstances:					
		Minimum	10,000	1989	89.361	8,936	18,936
		Maximum	100,000	1989	89.361	89,361	189,361
	45 CFR 93, Appendix A	Penalty for failure to provide certification regarding lobbying in the award documents for all subawards of all tiers:					
		Minimum	10,000	1989	89.361	8,936	18,936
		Maximum	100,000	1989	89.361	89,361	189,361

CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description[2]	Pre-inflation penalty ($)	Date of last penalty figure or adjustment[3]	Percentage increase[4]	Increase ($)[5]	Maximum adjusted penalty ($)
U.S.C.	CFR[1]						
		Penalty for failure to provide statement regarding lobbying for loan guarantee and loan insurance transactions:					
		Minimum	10,000	1989	89.361	8,936	18,936
		Maximum	100,000	1989	89.361	89,361	189,361
3801–3812	45 CFR 79.3(a)(1(iv)	Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.	5,000	1988	97.869	4,894	9,894
	45 CFR 79.3(b)(1)(ii)	Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.	5,000	1988	97.869	4,894	9,894

[1] Some HHS components have not promulgated regulations regarding their civil monetary penalties-specific statutory authorities.

[2] The description is not intended to be a comprehensive explanation of the underlying violation; the statute and corresponding regulation, if applicable, should be consulted.

[3] Statutory, or non-Inflation Act Adjustment.

[4] Based on the lesser of the CPI–U multiplier for October 2015, or 150%.

[5] Rounded to the nearest dollar.

III. Environmental Impact

HHS has determined that this interim final rule (IFR) does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental impact assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) and its implementing regulations (5 CFR part 1320), HHS reviewed this IFR and determined that there are no new collections of information contained therein.

V. Regulatory Flexibility Act

When an agency promulgates a final rule under 5 U.S.C. 553, after being required by that section or any other law to publish a general notice of proposed rulemaking, the Regulatory Flexibility Act (RFA) mandates that the agency prepare an RFA analysis. 5 U.S.C. 604(a). An RFA analysis is not required when a rule is exempt from notice and comment rulemaking under 5 U.S.C. 553(b). This interim final rule is exempt from notice and comment rulemaking. Therefore, no RFA analysis is required under 5 U.S.C. 604 and none was prepared.

VI. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Agencies must prepare a regulatory impact analysis for major rules with economically significant effects ($100 million or more in any 1 year). HHS has determined that this IFR is not economically significant.

HHS analyzed the economic significance of this IFR, by collecting data for fiscal years 2010 through 2014 on the total value of civil monetary penalties collected by Operating/Staff Divisions, except in the case of CMS, for which HHS used collections data through FY 2015. Such data included the statutory authority for the civil monetary penalty, which HHS used to apply the appropriate multiplier for each of the penalties collected. With respect to CMS, HHS determined the multiplier for the CMS collections by pro rating all of the multipliers for the civil monetary penalty authorities attributed to CMS.

HHS then applied the multiplier to collections for each Fiscal Year (2010 through 2014) to calculate the collections for each Fiscal Year with the inflation adjustment. HHS also performed an additional calculation for FY 2014/2015 using the inflated collections amount for FY 2015 for CMS and using the inflated collections amount for all other Operating/Staff Divisions for FY 2014. When collections were adjusted for inflation, the Department's lowest collection amount was $58,332,000 for FY 2012 and the highest total was $168,000,000 for FY 2014/2015.

Finally, HHS subtracted the collections value for a Fiscal Year (for example, FY 2010) from the collections value for the same Fiscal Year with the inflation adjustment (for example, FY 2010 with inflation adjustment) to assess the economic significance of this IFR for that Fiscal Year (for example, FY 2010 Economic Significance). When the calculations were completed, the Fiscal Year Economic Significance values ranged from a low of $23,698,917 for FY 2013, to a high of $70,913,713 for FY 2014/2015. Based on these calculations, HHS does not believe this IFR will be economically significant as defined in Executive Order 12866.

VII. Unfunded Mandates Reform Act of 1995 Determination

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires that covered agencies prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. HHS has determined that this IFR does not result in expenditures by State, local, and tribal governments, or by the private sector, of $100 million or more in any one year. Accordingly, HHS has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

VIII. Executive Order 13132 Determination

HHS has determined that this IFR does not have any Federalism implications, as required by Executive Order 13132.

List of Subjects

42 CFR Part 3

Administrative practice and procedure, Conflicts of interests, Health records, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 402

Administrative practice and procedure, Medicaid, Medicare, Penalties.

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 438

Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 493

Administrative practice and procedure, Grant programs—health, Health facilities, Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 1003

Fraud, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping.

45 CFR Part 79

Administrative practice and procedure, Claims, Fraud, Penalties.

45 CFR Part 93

Government contracts, Grants programs, Loan programs, Lobbying, Penalties.

45 CFR Part 102

Administrative practice and procedure, Penalties.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interest, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs—health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety, State and local governments, Technical assistance, Women, and Youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interest, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs—health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, penalties, Reporting and recordkeeping requirements, Premium revenues, Medical loss ratio, Rebating.

45 CFR Part 160

Administrative practice and procedures, Penalties, Records and recordkeeping requirements.

45 CFR Part 303

Child support, Standards for program operations, Penalties.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR chapter I and 45 CFR subtitle A, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV, the Office of the Inspector General amends 42 CFR chapter 42 CFR chapter V, and the Administration for Children and Families amends 45 CFR chapter III as follows:

Title 42—Public Health

Chapter I—Public Health Service, Department of Health and Human Services

PART 3—PATIENT SAFETY ORGANIZATIONS AND PATIENT SAFETY WORK PRODUCT

■ 1. The authority citation for part 3 continues to read as follows:

Authority: 42 U.S.C. 216, 299b–21 through 299b–26; 42 U.S.C. 299c–6.

■ 2. Section 3.404 is revised to read as follows:

§ 3.404 Amount of a civil money penalty.

(a) The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section and § 3.408.

(b) The Secretary may impose a civil monetary penalty in the amount of not more than $11,000. This amount has been updated and will be updated annually, in accordance with the Federal Civil Monetary penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). The amount, as updated, is published at 45 CFR part 102.

CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

■ 3. The authority citation for part 402 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 402.105 [Amended]

■ 4. In the table below, § 402.105 is amended in each paragraph indicated in the first column, by removing the phrase indicated in the second column and adding in its place the phrase in the third column:

Paragraph	Remove	Add
(a)	"$2,000 for each service"	"$2,000 as adjusted annually under 45 CFR part 102 for each service".
(b) introductory text	"not more than $1,000 for"	"not more than $1,000 as adjusted annually under 45 CFR part 102 for".
(c) introductory text	"not more than $5,000 for"	"not more than $5,000 as adjusted annually under 45 CFR part 102 for".
(d)(1)	"not more than $10,000 for"	"not more than $10,000 as adjusted annually under 45 CFR part 102 for".
(d)(2) introductory text	"not more than $10,000 for"	"not more than $10,000 as adjusted annually under 45 CFR part 102 for".
(d)(3)	"not more than $10,000 for"	"not more than $10,000 as adjusted annually under 45 CFR part 102 for".
(d)(4)	"not more than $10,000 for"	"not more than $10,000 as adjusted annually under 45 CFR part 102 for".
(d)(5)	"not more than $10,000 for"	"not more than $10,000 as adjusted annually under 45 CFR part 102 for".
(d)(5)	"will not exceed $150,000"	"will not exceed $150,000 as annually adjusted under 45 CFR part 102".
(e)	"not more than $15,000 for"	"not more than $15,000 as adjusted annually under 45 CFR part 102 for".
(f) introductory text	"not more than $25,000 for"	"not more than $25,000 as adjusted annually under 45 CFR part 102 for".
(g)	"not more than $100 for"	"not more than $100 as adjusted annually under 45 CFR part 102 for".
(h)	"not more than $100,000 for"	"not more than $10,000 as adjusted annually under 45 CFR part 102 for".
(h)	"will not exceed $1,000,000"	"will not exceed $1,000,000 as annually adjusted under 45 CFR part 102".

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 5. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1395b–3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 403.912 [Amended]

■ 6. In the table below, § 403.912 is amended in each paragraph indicated in the first column, by removing the phrase indicated in the third column and adding in its place the phrase indicated in the fourth column:

Paragraph	Remove	Add
(a)(1)	"not less than $1,000, but not more than $10,000 for".	"not less than $10,000, but not more than $100,000, as adjusted annually under 45 CFR part 102 for".
(a)(2)	"will not exceed $150,000"	"will not exceed $150,000 as adjusted annually under 45 CFR part 102".
(b)(1)	"not less than $10,000, but not more than $100,000 for".	"not less than $10,000, but not more than $100,000, as adjusted annually under 45 CFR part 102 for".
(b)(2)	"will not exceed $1,000,000"	"will not exceed $1,000,000 as adjusted annually under 45 CFR part 102".
(c)(2)	"with a maximum combined annual total of $1,150,000".	"with a maximum combined annual total of $1,150,000 as adjusted annually under 45 CFR part 102".

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 7. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

§§ 411.103 and 411.361 [Amended]

■ 8. In the table below, for each section and paragraph indicated in the first two columns, remove the phrase indicated in the third column and add in its place the phrase indicated in the fourth column:

Section	Paragraphs	Remove	Add
§ 411.103	(b)(1)	"up to $5,000 for"	"up to $5,000 as adjusted annually under 45 CFR part 102 for".
	(b)(2)	"up to $5,000"	"up to $5,000 as adjusted annually under 45 CFR part 102".
§ 411.361	(f)	"up to $10,000 for"	"up to $10,000 as adjusted annually under 45 CFR part 102 for".

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 12. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 1206 of Pub. L. 113–67, and sec. 112 of Pub. L. 113–93.

§ 412.612 [Amended]

■ 13. Section 412.612 is amended as follows:

■ a. In paragraph (b)(1)(i), by removing the phrase "not more than $1,000 for" and adding in its place the phrase "not more than $1,000 as adjusted annually under 45 CFR part 102 for"; and

■ b. In paragraph (b)(1)(ii), by removing the phrase "not more than $5,000 for" and adding in its place the phrase "not more than $5,000 as adjusted annually under 45 CFR part 102 for".

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 14. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 422.760 [Amended]

■ 15. In the table below, § 422.760 is amended in each paragraph indicated in the first column, by removing the phrase indicated in the second column and add in its place the phrase indicated in the third column:

Paragraph	Remove	Add
(b)(1)	"up to $25,000 for each"	"up to $25,000 as adjusted annually under 45 CFR part 102 for each".
(b)(2)	"up to $25,000 for each"	"up to $25,000 as adjusted annually under 45 CFR part 102 for each".
(b)(3)	"determination—up to $10,000"	"determination—up to $10,000 as adjusted annually under 45 CFR part 102".
(b)(4)	"$250 per Medicare enrollee"	"$250 as adjusted annually under 45 CFR part 102 per Medicare enrollee".
(b)(4)	"or $100,000, whichever is greater".	"or $100,000 as adjusted annually under 45 CFR part 102, whichever is greater".
(c)(1)	"not more than $25,000 for"	"not more than $25,000 as adjusted annually under 45 CFR part 102 for".
(c)(2)	"not more than $100,000 for"	"not more than $100,000 as adjusted annually under 45 CFR part 102 for".
(c)(4)	"$15,000 for each individual"	"$15,000 as adjusted annually under 45 CFR part 102 for each individual".

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 16. The authority citation for part 423 continues to read as follows:

Authority: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

§ 423.760 [Amended]

■ 17. In the table below, § 423.760 is amended in each paragraph indicated by the first column, by removing the phrase indicated in the second column and add in its place the phrase indicated in the third column:

Paragraph	Remove	Add
(b)(1)	"enrollees—up to $25,000 for each determination".	"enrollees—up to $25,000 as adjusted annually under 45 CFR part 102 for each determination".
(b)(2)	"of up to $25,000 for each Part D enrollee".	"of up to $25,000 as adjusted annually under 45 CFR part 102 for each Part D enrollee".
(b)(3)	"up to $10,000"	"up to $10,000 as adjusted annually under 45 CFR part 102".
(b)(4)	"$250 per Medicare enrollee"	"$250 as adjusted annually under 45 CFR part 102 per Medicare enrollee".
(b)(4)	"or $100,000, whichever is greater".	"or $100,000 as adjusted annually under 45 CFR part 102, whichever is greater".
(c)(1)	"of not more than $25,000 for each".	"of not more than $25,000 as adjusted annually under 45 CFR part 102 for each".

Paragraph	Remove	Add
(c)(2)	"not more than $100,000 for each"	"not more than $100,000 as adjusted annually under 45 CFR part 102 for each".
(c)(4)	"$15,000 for each individual"	"$15,000 as adjusted annually under 45 CFR part 102 for each individual".

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 18. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102, 1128I, 1819, 1871 and 1919 of the Social Security Act (42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r).

§ 483.20 [Amended]

■ 19. Section 483.20 is amended as follows:

■ a. In paragraph (j)(1)(i), by removing the phrase "not more than $1,000 for" and adding in its place the phrase "not more than $1,000 as adjusted annually under 45 CFR part 102 for"; and

■ b. In paragraph (j)(1)(ii), by removing the phrase "not more than $5,000 for" and adding it its place the phrase "not more than $5,000 as adjusted annually under 45 CFR part 102 for".

§ 483.151 [Amended]

■ 20. Section 483.151 is amended as follows:

■ a. In paragraph (b)(2)(iv), by removing the phrase "not less than $5,000; or" and adding in its place the phrase "not less than $5,000 as adjusted annually under 45 CFR part 102; or";

■ b. In paragraph (b)(3)(iii), by removing the phrase "not less than $5,000 for" and adding in its place the phrase "not less than $5,000 as adjusted annually under 45 CFR part 102 for"; and

■ c. In paragraph (c)(1), by removing the phrase "not less than $5,000" and adding in its place the phrase "not less than $5,000 as adjusted annually under 45 CFR part 102".

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 21. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1128l, 1864, 1865, 1871 and 1875 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302, 1320a–7j, 1395aa, 1395bb, 1395hh) and 1395ll.

§§ 488.307, 488.408, 488.438, 488.446, 488.725, and 488.845 [Amended]

■ 22. In the table below, for each section and paragraph indicated in the first two columns, remove the phrase indicated in the third column and add in its place the phrase indicated in the fourth column:

Section	Paragraph	Remove	Add
488.307	(c)	"not to exceed $2,000"	"not to exceed $2,000 as adjusted annually under 45 CFR part 102".
488.408	(d)(1)(iii)	"$50–$3,000 per day"	"$50–$3,000 as adjusted annually under 45 CFR part 102 per day".
	(d)(1)(iv)	"$1,000–$10,000 per instance".	"$1,000–$10,000 as adjusted annually under 45 CFR part 102 per instance".
	(e)(1)(iii)	"$3,050–$10,000 per day"	"$3,050–$10,000 as adjusted annually under 45 CFR part 102 per day".
	(e)(1)(iv)	"$1,000–$10,000 per instance".	"$1,000–$10,000 as adjusted annually under 45 CFR part 102 per instance".
	(e)(2)(ii)	"3,050–$10,000 per day or $1,000–$10,000 per instance".	"3,050–$10,000 as adjusted annually under 45 CFR part 102 per day or $1,000–$10,000 as adjusted annually under 45 CFR part 102 per instance".
488.438	(a)(1)(i)	"Upper range—$3,050–$10,000".	"Upper range".
	(a)(1)(i)	"$3,050–$10,000 per day"	"$3,050–$10,000 as adjusted annually under 45 CFR part 102 per day".
	(a)(1)(ii)	"Lower range—$50–$3,000".	"Upper range".
	(a)(1)(ii)	"$50–$3,000 per day"	"$50–$3,000 as adjusted annually under 45 CFR part 102 per day".
	(a)(2)	"$1,000–$10,000 per instance".	"$1,000–$10,000 as adjusted annually under 45 CFR part 102 per instance".
488.446	(a)(1)	"A minimum of $500 for"	"A minimum of $500 as adjusted annually under 45 CFR part 102 for".
	(a)(2)	"A minimum of $1,500 for"	"A minimum of $1,500 as adjusted annually under 45 CFR part 102 for".
	(a)(3)	"A minimum of $3,000 for"	"A minimum of $3,000 as adjusted annually under 45 CFR part 102 for".
488.725	(c)	"not to exceed $2,000"	"not to exceed $2,000 as adjusted annually under 45 CFR part 102".
488.845	(b)(2)(iii)	"shall exceed $10,000 for"	"will exceed $10,000 as adjusted under 45 CFR part 102 for".
	(b)(3) introductory text	"upper range of $8,500 to $10,000 per day".	"upper range of $8,500 to $10,000 as adjusted annually under 45 CFR part 102 per day".
	(b)(3)(i)	"$10,000 per day"	"$10,000 as adjusted annually under 45 CFR part 102 per day".
	(b)(3))(ii)	"$9,000 per day"	"$9,000 as adjusted annually under 45 CFR part 102 per day".

Section	Paragraph	Remove	Add
	(b)(3)(iii)	“$8,500 per day”	“$8,500 as adjusted annually under 45 CFR part 102 per day”.
	(b)(4)	“range of $1,500–$8,500 per day”.	“range of $1,500–$8,500 as adjusted annually under 45 CFR part 102 per day”.
	(b)(5)	“range of $500–$4,000 are imposed”.	“range of $500–$4,000 as adjusted annually under 45 CFR part 102 are imposed”.
	(b)(6)	“range of $1,000 to $10,000 per instance, not to exceed $10,000 each day”.	“range of $1,000 to $10,000 as adjusted annually under 45 CFR part 102 per instance, not to exceed $10,000 as adjusted annually under 45 CFR part 102 each day”.
	(d)(1)(ii)	“maximum of $10,000 per day”.	“maximum of $10,000 as adjusted annually under 45 CFR part 102 per day”.

PART 493—LABORATORY REQUIREMENTS

■ 23. The authority citation for part 493 continues to read as follows:

Authority: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)), and the Pub. L. 112–202 amendments to 42 U.S.C. 263a.

§ 493.1834 [Amended]

■ 24. Section 493.1834 is amended as follows:

■ a. In paragraph (d)(2)(i), by removing the phrase “$3,050–$10,000 per day” and adding in its place the phrase “$3,050–$10,000 as adjusted annually under 45 CFR part 102 per day”; and

■ b. In paragraph (d)(2)(ii), by removing the phrase “$50–$3,000 per day” and adding in its place the phrase “$50–$3,000 as adjusted annually under 45 CFR part 102 per day”.

CHAPTER V—OFFICE OF INSPECTOR GENERAL—HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

■ 25. The authority citation for part 1003 continues to read as follows:

Authority: 42 U.S.C. 262a, 1302, 1320–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395cc(j), 1395w–141(i)(3), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

§ 1003.103 [Amended]

■ 26. Section 1003.103 is amended:

■ a. In paragraph (c)—

■ i. By removing the footnote in paragraph (c); and

■ ii. In paragraph (c) by removing the phrase “not more than $11,000 for each payment” and adding in its place the phrase “not more than $10,000 for each payment”; and

■ b. In the table below, § 1003.103 is further amended in each paragraph indicated by the first column by adding the footnote in the third column after the phrase in the second column:

Paragraph	Text	Add footnote
(a)(1)	“$2,000”	“1. This penalty amount is updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). Annually adjusted amounts are published at 45 CFR part 102.”
(a)(2)	“$10,000”	“2. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(b)	“not more than $15,000”	“3. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
	“not more than $100,000”	“4. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(c)	“not more than $10,000”	“5. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(d)(1)	“not more than $5,000”	“6. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
	“not more than $25,000”	“7. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(e)(1)	“not more than $50,000”	“8. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
	“will not exceed $25,000;”	“9. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(e)(2)	“not more than $50,000”	“10. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(f)(1) introductory text	“up to $25,000”	“11. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(f)(2) introductory text	“up to $25,000”	“12. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(f)(3) introductory text	“up to $100,000”	“13. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(f)(5)	“an additional $15,000”	“14. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(g)	“not more than $25,000”	“15. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”

Paragraph	Text	Add footnote
(h)(1)	"not more than $50,000"	"16. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102."
(h)(2)(i)(1)	"$5,000"	"17. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102."
(j)	"not more than $10,000"	"18. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102."
(k)	"not more than $2,000"	"19. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102."
(l)	"not more than $250,000"	"20. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102."
(l)	"and not more than $500,000"	"21. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102."
(m)	"not more than $10,000"	"22. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102."

Title 45—Public Welfare

Subtitle A—Department of Health and Human Services

PART 79—PROGRAM FRAUD CIVIL PENALTIES

■ 27. The authority for part 79 continues to read as follows:

Authority: 31 U.S.C. 3801–3812.

■ 28. In § 79.3, paragraph (a)(1)(iv) is amended by revising footnote 1 and paragraph (b)(1)(ii) is amended by revising footnote 2 to read as follows:

§ 79.3 Basis for civil penalties and assessments.

(a) * * *

(1) * * *

(iv) * * *

[1] The amounts specified in this section are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). Annually adjusted amounts are published at 45 CFR part 102.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

[2] The amounts specified in this section are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). Annually adjusted amounts are published at 45 CFR part 102.

* * * * *

PART 93—NEW RESTRICTIONS ON LOBBYING

■ 29. The authority for part 93 continues to read as follows:

Authority: Section 319, Public Law 101–121 (31 U.S.C. 1352); (5 U.S.C. 301).

■ 30. Section § 93.400 is amended in paragraph (a) by adding a footnote at the end of the phrase "not less than $10,000 and not more than $100,000" to read as follows:

§ 93.400 Penalties.

(a) * * *

[1] The amounts specified in this section are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). Annually adjusted amounts are published at 45 CFR part 102.

* * * * *

■ 31. Appendix A to part 93 is amended in the undesignated paragraph following paragraph (3), under "Certification for Contracts, Grants, Loans, and Cooperative Agreements," by adding a footnote at the end of the phrase "of not less than $10,000 and not more than 100,000" to read as follows:

Appendix A—Certification Regarding Lobbying

Certification for Contracts, Grants, Loans, and Cooperative Agreements

* * * * *

(3) * * *

[1] The amounts specified in Appendix A to Part 93 are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). Annually adjusted amounts are published at 45 CFR part 102.

* * * * *

■ 32. Part 102 is added to subchapter A to read as follows:

PART 102—ADJUSTMENT OF CIVIL MONETARY PENALTIES FOR INFLATION

Sec.

102.1 Applicability.
102.2 Applicability date.
102.3 Penalty adjustment and table.

Authority: Public Law 101–410, Sec. 701 of Public Law 114–74, 31 U.S.C. 3801–3812.

§ 102.1 Applicability.

This part applies to each statutory provision under the laws administered by the Department of Health and Human Services concerning the civil monetary penalties which may be assessed or enforced by an agency pursuant to Federal law or is assessed or enforced pursuant to civil judicial actions in the Federal courts or administrative proceedings. The regulations cited in this part supersede existing HHS regulations setting forth civil monetary penalty amounts. If applicable, the HHS agencies responsible for specific civil monetary penalties will amend their regulations to reflect the adjusted amounts and/or a cross-reference to 45 CFR part 102 in separate actions as soon as practicable.

§ 102.2 Applicability date.

The increased penalty amounts set forth in the right-most column of the table in Section 102.3, "Maximum Adjusted Penalty ($)", apply to all civil monetary penalties which are assessed after August 1, 2016, including those penalties whose associated violations occurred after November 2, 2015.

§ 102.3 Penalty adjustment and table.

The adjusted statutory penalty provisions and their applicable amounts are set out in the following table. The right-most column in the table, "Maximum Adjusted Penalty ($)", provides the maximum adjusted civil penalty amounts. The civil monetary penalty amounts are adjusted annually.

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS

[Effective September 6, 2016]

Citation		HHS agency	Description [2]	Date of last penalty figure or adjustment [3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR [1]					
21 U.S.C.:						
333(b)(2)(A)		FDA	Penalty for violations related to drug samples resulting in a conviction of any representative of manufacturer or distributor in any 10-year period.	1988	50,000	98,935
333(b)(2)(B)		FDA	Penalty for violation related to drug samples resulting in a conviction of any representative of manufacturer or distributor after the second conviction in any 10-yr period.	1988	1,000,000	1,978,690
333(b)(3)		FDA	Penalty for failure to make a report required by 21 U.S.C. 353(d)(3)(E) relating to drug samples.	1988	100,000	197,869
333(f)(1)(A)		FDA	Penalty for any person who violates a requirement related to devices for each such violation.	1990	15,000	26,723
			Penalty for aggregate of all violations related to devices in a single proceeding.	1990	1,000,000	1,781,560
333(f)(2)(A)		FDA	Penalty for any individual who introduces or delivers for introduction into interstate commerce food that is adulterated per 21 U.S.C. 342(a)(2)(B) or any individual who does not comply with a recall order under 21 U.S.C. 350l.	1996	50,000	75,123
			Penalty in the case of any other person other than an individual) for such introduction or delivery of adulterated food.	1996	250,000	375,613
			Penalty for aggregate of all such violations related to adulterated food adjudicated in a single proceeding.	1996	500,000	751,225
333(f)(3)(A)		FDA	Penalty for all violations adjudicated in a single proceeding for any person who fails to submit certification required by 42 U.S.C. 282(j)(5)(B) or knowingly submitting a false certification.	2007	10,000	11,383
333(f)(3)(B)		FDA	Penalty for each day the above violation is not corrected after a 30-day period following notification until the violation is corrected.	2007	10,000	11,383
333(f)(4)(A)(i)		FDA	Penalty for any responsible person that violates a requirement of 21 U.S.C. 355(o) (post-marketing studies, clinical trials, labeling), 21 U.S.C. 355(p) (risk evaluation and mitigation (REMS)), or 21 U.S.C. 355–1 (REMS).	2007	250,000	284,583
			Penalty for aggregate of all such above violations in a single proceeding.	2007	1,000,000	1,138,330
333(f)(4)(A)(ii)		FDA	Penalty for REMS violation that continues after written notice to the responsible person for the first 30-day period (or any portion thereof) the responsible person continues to be in violation.	2007	250,000	284,583
			Penalty for REMS violation that continues after written notice to responsible person doubles for every 30-day period thereafter the violation continues, but may not exceed penalty amount for any 30-day period.	2007	1,000,000	1,138,330
			Penalty for aggregate of all such above violations adjudicated in a single proceeding.	2007	10,000,000	11,383,300
333(f)(9)(A)		FDA	Penalty for any person who violates a requirement which relates to tobacco products for each such violation.	2009	15,000	16,503
			Penalty for aggregate of all such violations of tobacco product requirement adjudicated in a single proceeding.	2009	1,000,000	1,100,200
333(f)(9)(B)(i)(I)		FDA	Penalty per violation related to violations of tobacco requirements.	2009	250,000	275,050
			Penalty for aggregate of all such violations of tobacco product requirements adjudicated in a single proceeding.	2009	1,000,000	1,100,200
333(f)(9)(B)(i)(II)		FDA	Penalty in the case of a violation of tobacco product requirements that continues after written notice to such person, for the first 30-day period (or any portion thereof) the person continues to be in violation.	2009	250,000	275,050

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued

[Effective September 6, 2016]

Citation		HHS agency	Description [2]	Date of last penalty figure or adjustment [3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR [1]					
			Penalty for violation of tobacco product requirements that continues after written notice to such person shall double for every 30-day period thereafter the violation continues, but may not exceed penalty amount for any 30-day period.	2009	1,000,000	1,100,200
			Penalty for aggregate of all such violations related to tobacco product requirements adjudicated in a single proceeding.	2009	10,000,000	11,002,000
333(f)(9)(B)(ii)(I)		FDA	Penalty for any person who either does not conduct post-market surveillance and studies to determine impact of a modified risk tobacco product for which the HHS Secretary has provided them an order to sell, or who does not submit a protocol to the HHS Secretary after being notified of a requirement to conduct post-market surveillance of such tobacco products.	2009	250,000	275,050
			Penalty for aggregate of for all such above violations adjudicated in a single proceeding.	2009	1,000,000	1,100,200
333(f)(9)(B)(ii)(II)		FDA	Penalty for violation of modified risk tobacco product post-market surveillance that continues after written notice to such person for the first 30-day period (or any portion thereof) that the person continues to be in violation.	2009	250,000	275,050
			Penalty for post-notice violation of modified risk tobacco product post-market surveillance shall double for every 30-day period thereafter that the tobacco product requirement violation continues for any 30-day period, but may not exceed penalty amount for any 30-day period.	2009	1,000,000	1,100,200
			Penalty for aggregate above tobacco product requirement violations adjudicated in a single proceeding.	2009	10,000,000	11,002,000
333(g)(1)		FDA	Penalty for any person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading for the first such violation in any 3-year period.	2007	250,000	284,583
			Penalty for each subsequent above violation in any 3-year period.	2007	500,000	569,165
333 note		FDA	Penalty to be applied for violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (*e.g.,* violations of regulations in 21 CFR Part 1140) with respect to a retailer with an approved training program in the case of a second regulation violation within a 12-month period.	2009	250	275
			Penalty in the case of a third tobacco product regulation violation within a 24-month period.	2009	500	550
			Penalty in the case of a fourth tobacco product regulation violation within a 24-month period.	2009	2,000	2,200
			Penalty in the case of a fifth tobacco product regulation violation within a 36-month period.	2009	5,000	5,501
			Penalty in the case of a sixth or subsequent tobacco product regulation violation within a 48-month period as determined on a case-by-case basis.	2009	10,000	11,002
			Penalty to be applied for violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (*e.g.,* violations of regulations in 21 CFR Part 1140) with respect to a retailer that does not have an approved training program in the case of the first regulation violation.	2009	250	275
			Penalty in the case of a second tobacco product regulation violation within a 12-month period.	2009	500	550

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued

[Effective September 6, 2016]

Citation		HHS agency	Description [2]	Date of last penalty figure or adjustment [3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR [1]					
			Penalty in the case of a third tobacco product regulation violation within a 24-month period.	2009	1,000	1,100
			Penalty in the case of a fourth tobacco product regulation violation within a 24-month period.	2009	2,000	2,200
			Penalty in the case of a fifth tobacco product regulation violation within a 36-month period.	2009	5,000	5,501
			Penalty in the case of a sixth or subsequent tobacco product regulation violation within a 48-month period as determined on a case-by-case basis.	2009	10,000	11,002
335b(a)		FDA	Penalty for each violation for any individual who made a false statement or misrepresentation of a material fact, bribed, destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document, failed to disclose a material fact, obstructed an investigation, employed a consultant who was debarred, debarred individual provided consultant services.	1992	250,000	419,320
			Penalty in the case of any other person (other than an individual) per above violation.	1992	1,000,000	1,677,280
360pp(b)(1)		FDA	Penalty for any person who violates any such requirements for electronic products, with each unlawful act or omission constituting a separate violation.	1968	1,100	2,750
			Penalty imposed for any related series of violations of requirements relating to electronic products.	1968	375,000	937,500
42 U.S.C.:						
262(d)		FDA	Penalty per day for violation of order of recall of biological product presenting imminent or substantial hazard.	1986	100,000	215,628
263b(h)(3)		FDA	Penalty for failure to obtain a mammography certificate as required.	1992	10,000	16,773
300aa–28(b)(1)		FDA	Penalty per occurrence for any vaccine manufacturer that intentionally destroys, alters, falsifies, or conceals any record or report required.	1986	100,000	215,628
256b(d)(1)(B)(vi)		HRSA	Penalty for each instance of overcharging a 340B covered entity.	2010	5,000	5,437
299c–(3)(d)		AHRQ	Penalty for an establishment or person supplying information obtained in the course of activities for any purpose other than the purpose for which it was supplied.	1999	10,000	14,140
653(l)(2)	45 CFR 303.21(f)	ACF	Penalty for Misuse of Information in the National Directory of New Hires.	1998	1,000	1,450
262a(i)(1)	42 CFR Part 1003	OIG	Penalty for each individual who violates safety and security procedures related to handling dangerous biological agents and toxins.	2002	250,000	327,962
			Penalty for any other person who violates safety and security procedures related to handling dangerous biological agents and toxins..	2002	500,000	655,925
1320a–7a(a)	42 CFR Part 1003	OIG	Penalty for knowingly presenting or causing to be presented to an officer, employee, or agent of the United States a false claim.	1996	10,000	15,024
			Penalty for knowingly presenting or causing to be presented a request for payment which violates the terms of an assignment, agreement, or PPS agreement.	1996	10,000	15,024
			Penalty for knowingly giving or causing to be presented to a participating provider or supplier false or misleading information that could reasonably be expected to influence a discharge decision.	1996	15,000	22,537
			Penalty for an excluded party retaining ownership or control interest in a participating entity.	1996	10,000	15,024
			Penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.	1996	10,000	15,024

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued

[Effective September 6, 2016]

Citation		HHS agency	Description[2]	Date of last penalty figure or adjustment[3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR[1]					
			Penalty for employing or contracting with an excluded individual.	1997	10,000	14,718
			Penalty for knowing and willful solicitation, receipt, offer, or payment of remuneration for referring an individual for a service or for purchasing, leasing, or ordering an item to be paid for by a Federal health care program.	1997	50,000	73,588
			Penalty for ordering or prescribing medical or other item or service during a period in which the person was excluded.	2010	10,000	10,874
			Penalty for knowingly making or causing to be made a false statement, omission or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider or supplier.	2010	50,000	54,372
			Penalty for knowing of an overpayment and failing to report and return.	2010	10,000	10,874
			Penalty for making or using a false record or statement that is material to a false or fraudulent claim.	2010	50,000	54,372
			Penalty for failure to grant timely access to HHS OIG for audits, investigations, evaluations, and other statutory functions of HHS OIG.	2010	15,000	16,312
1320a–7a(b)	42 CFR Part 1003	OIG	Penalty for payments by a hospital or critical access hospital to induce a physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	1986	2,000	4,313
			Penalty for physicians who knowingly receive payments from a hospital or critical access hospital to induce such physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	1986	2,000	4,313
			Penalty for a physician who executes a document that falsely certifies home health needs for Medicare beneficiaries.	1996	5,000	7,512
1320a–7e(b)(6)(A)	42 CFR Part 1003	OIG	Penalty for failure to report any final adverse action taken against a health care provider, supplier, or practitioner.	1997	25,000	36,794
1320b–10(b)(1)	42 CFR Part 1003	OIG	Penalty for the misuse of words, symbols, or emblems in communications in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS.	1988	5,000	9,893
1320b–10(b)(2)	42 CFR Part 1003	OIG	Penalty for the misuse of words, symbols, or emblems in a broadcast or telecast in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS.	1988	25,000	49,467
1395i–3(b)(3)(B)(ii)(1)		OIG	Penalty for certification of a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	1987	1,000	2,063
1395i–3(b)(3)(B)(ii)(2)		OIG	Penalty for causing another to certify or make a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	1987	5,000	10,314
1395i–3(g)(2)(A)		OIG	Penalty for any individual who notifies or causes to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted.	1987	2,000	4,126
1395w–27(g)(2)(A)	42 CFR 422.752; 42 CFR Part 1003.	OIG	Penalty for a Medicare Advantage organization that substantially fails to provide medically necessary, required items and services.	1996	25,000	37,561
			Penalty for a Medicare Advantage organization that charges excessive premiums.	1997	25,000	36,794
			Penalty for a Medicare Advantage organization that improperly expels or refuses to reenroll a beneficiary.	1997	25,000	36,794
			Penalty for a Medicare Advantage organization that engages in practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	1997	100,000	147,177

Civil Monetary Penalty Authorities Administered by HHS Agencies and Penalty Amounts—Continued

[Effective September 6, 2016]

Citation		HHS agency	Description [2]	Date of last penalty figure or adjustment [3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR [1]					
			Penalty per individual who does not enroll as a result of a Medicare Advantage organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	1997	15,000	22,077
			Penalty for a Medicare Advantage organization misrepresenting or falsifying information to Secretary.	1997	100,000	147,177
			Penalty for a Medicare Advantage organization misrepresenting or falsifying information to individual or other entity.	1997	25,000	36,794
			Penalty for Medicare Advantage organization interfering with provider's advice to enrollee and non-MCO affiliated providers that balance bill enrollees.	1997	25,000	36,794
			Penalty for a Medicare Advantage organization that employs or contracts with excluded individual or entity.	1997	25,000	36,794
			Penalty for a Medicare Advantage organization enrolling an individual in without prior written consent.	2010	25,000	36,794
			Penalty for a Medicare Advantage organization transferring an enrollee to another plan without consent or solely for the purpose of earning a commission.	2010	25,000	36,794
			Penalty for a Medicare Advantage organization failing to comply with marketing restrictions or applicable implementing regulations or guidance.	2010	25,000	36,794
			Penalty for a Medicare Advantage organization employing or contracting with an individual or entity who violates 1395w–27(g)(1)(A)–(J).	2010	25,000	36,794
1395w–141(i)(3)	42 CFR Part 1003	OIG	Penalty for a prescription drug card sponsor that falsifies or misrepresents marketing materials, overcharges program enrollees, or misuse transitional assistance funds.	2003	10,000	12,856
1395cc(g)	42 CFR Part 1003	OIG	Penalty for improper billing by Hospitals, Critical Access Hospitals, or Skilled Nursing Facilities.	1972	2,000	5,000
1395dd(d)(1)	42 CFR Part 1003	OIG	Penalty for a hospital or responsible physician dumping patients needing emergency medical care, if the hospital has 100 beds or more.	1987	50,000	103,139
			Penalty for a hospital or responsible physician dumping patients needing emergency medical care, if the hospital has less than 100 beds.	1987	25,000	51,570
1395mm(i)(6)(B)(i)	42 CFR Part 1003	OIG	Penalty for a HMO or competitive plan is such plan substantially fails to provide medically necessary, required items or services.	1987	25,000	51,570
			Penalty for HMOs/competitive medical plans that charge premiums in excess of permitted amounts.	1987	25,000	51,570
			Penalty for a HMO or competitive medical plan that expels or refuses to reenroll an individual per prescribed conditions.	1987	25,000	51,570
			Penalty for a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in future.	1987	100,000	206,278
			Penalty per individual not enrolled in a plan as a result of a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in the future.	1988	15,000	29,680
			Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to the Secretary.	1987	100,000	206,278
			Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to an individual or any other entity.	1987	25,000	51,570
			Penalty for failure by HMO or competitive medical plan to assure prompt payment of Medicare risk sharing contracts or incentive plan provisions.	1987	25,000	51,570

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued

[Effective September 6, 2016]

Citation		HHS agency	Description[2]	Date of last penalty figure or adjustment[3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR[1]					
			Penalty for HMO that employs or contracts with excluded individual or entity.	1989	25,000	47,340
1395nn(g)(3)	42 CFR Part 1003	OIG	Penalty for submitting or causing to be submitted claims in violation of the Stark Law's restrictions on physician self-referrals.	1994	15,000	23,863
1395nn(g)(4)	42 CFR Part 1003	OIG	Penalty for circumventing Stark Law's restrictions on physician self-referrals.	1994	100,000	159,089
1395ss(d)(1)	42 CFR Part 1003	OIG	Penalty for a material misrepresentation regarding Medigap compliance policies.	1988	5,000	9,893
1395ss(d)(2)	42 CFR Part 1003	OIG	Penalty for selling Medigap policy under false pretense.	1988	5,000	9,893
1395ss(d)(3)(A)(ii)	42 CFR Part 1003	OIG	Penalty for an issuer that sells health insurance policy that duplicates benefits.	1990	25,000	44,539
			Penalty for someone other than issuer that sells health insurance that duplicates benefits.	1990	15,000	26,723
1395ss(d)(4)(A)	42 CFR Part 1003	OIG	Penalty for using mail to sell a non-approved Medigap insurance policy.	1988	5,000	9,893
1396b(m)(5)(B)(i)	42 CFR Part 1003	OIG	Penalty for a Medicaid MCO that substantially fails to provide medically necessary, required items or services.	1988	25,000	49,467
			Penalty for a Medicaid MCO that charges excessive premiums.	1988	25,000	49,467
			Penalty for a Medicaid MCO that improperly expels or refuses to reenroll a beneficiary.	1988	100,000	197,869
			Penalty per individual who does not enroll as a result of a Medicaid MCO's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	1988	15,000	29,680
			Penalty for a Medicaid MCO misrepresenting or falsifying information to the Secretary.	1988	100,000	197,869
			Penalty for a Medicaid MCO misrepresenting or falsifying information to an individual or another entity.	1988	25,000	49,467
			Penalty for a Medicaid MCO that fails to comply with contract requirements with respect to physician incentive plans.	1990	25,000	44,539
1396r(b)(3)(B)(ii)(I)	42 CFR Part 1003	OIG	Penalty for willfully and knowingly certifying a material and false statement in a Skilled Nursing Facility resident assessment.	1987	1,000	2,063
1396r(b)(3)(B)(ii)(II)	42 CFR Part 1003	OIG	Penalty for willfully and knowingly causing another individual to certify a material and false statement in a Skilled Nursing Facility resident assessment.	1987	5,000	10,314
1396r(g)(2)(A)(i)	42 CFR Part 1003	OIG	Penalty for notifying or causing to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted.	1987	2,000	4,126
1396r–8(b)(3)(B)	42 CFR Part 1003	OIG	Penalty for the knowing provision of false information or refusing to provide information about charges or prices of a covered outpatient drug.	1990	100,000	178,156
1396r–8(b)(3)(C)(i)	42 CFR Part 1003		Penalty per day for failure to timely provide information by drug manufacturer with rebate agreement.	1990	10,000	17,816
1396r–8(b)(3)(C)(ii)	42 CFR Part 1003		Penalty for knowing provision of false information by drug manufacturer with rebate agreement.	1990	100,000	178,156
1396t(i)(3)(A)	42 CFR Part 1003	OIG	Penalty for notifying home and community-based providers or settings of survey.	1990	2,000	3,563
11131(c)	42 CFR Part 1003	OIG	Penalty for failing to report a medical malpractice claim to National Practitioner Data Bank.	1986	10,000	21,563
11137(b)(2)	42 CFR Part 1003	OIG	Penalty for breaching confidentiality of information reported to National Practitioner Data Bank.	1986	10,000	21,563
299b–22(f)(1)	42 CFR 3.404	OCR	Penalty for violation of confidentiality provision of the Patient Safety and Quality Improvement Act.	2005	10,000	11,940
1320(d)–5(a)	45 CFR 160.404(b)(1)(i),(ii)	OCR	Penalty for each pre-February 18, 2009 violation of the HIPAA administrative simplification provisions.	1996	100	150
			Calendar Year Cap	1996	25,000	37,561

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued

[Effective September 6, 2016]

Citation		HHS agency	Description[2]	Date of last penalty figure or adjustment[3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR[1]					
1320(d)–5(a)	45 CFR 160.404(b)(2)(i)(A), (B).	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the covered entity or business associate did not know and by exercising reasonable diligence, would not have known that the covered entity or business associate violated such a provision:			
			Minimum	2009	100	110
			Maximum	2009	50,000	55,010
			Calendar Year Cap	2009	1,500,000	1,650,300
	45 CFR 160.404(b)(2)(ii)(A), (B).	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to reasonable cause and not to willful neglect:			
			Minimum	2009	1,000	1,100
			Maximum	2009	50,000	55,010
			Calendar Year Cap	2009	1,500,000	1,650,300
	45 CFR 160.404(b)(2)(iii)(A), (B).	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to willful neglect and was corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or, by exercising reasonable diligence, would have known that the violation occurred:			
			Minimum	2009	10,000	11,002
			Maximum	2009	50,000	55,010
			Calendar Year Cap	2009	1,500,000	1,650,300
	45 CFR 160.404(b)(2)(iv)(A), (B).	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or by exercising reasonable diligence, would have known that the violation occurred:			
			Minimum	2009	50,000	55,010
			Maximum	2009	1,500,000	1,650,300
			Calendar Year Cap	2009	1,500,000	1,650,300
263a(h)(2)(B) & 1395w–2(b)(2)(A)(ii).	42 CFR 493.1834(d)(2)(i)	CMS	Penalty for a clinical laboratory's failure to meet participation and certification requirements and poses immediate jeopardy:			
			Minimum	1988	3,050	6,035
			Maximum	1988	10,000	19,787
	42 CFR 493.1834(d)(2)(ii)	CMS	Penalty for a clinical laboratory's failure to meet participation and certification requirements and the failure does not pose immediate jeopardy:			
			Minimum	1988	50	99
			Maximum	1988	3,000	5,936
300gg–15(f)	45 CFR 147.200(e)	CMS	Failure to provide the Summary of Benefits and Coverage.	2010	1,000	1,087
300gg–18	45 CFR 158.606	CMS	Penalty for violations of regulations related to the medical loss ratio reporting and rebating.	2010	100	109
1320a–7h(b)(1)	42 CFR 402.105(d)(5); 42 CFR 403.912(a) & (c).	CMS	Penalty for manufacturer or group purchasing organization failing to report information required under 42 U.S.C. 1320a–7h(a), relating to physician ownership or investment interests:			
			Minimum	2010	1,000	1,087
			Maximum	2010	10,000	10,874
			Calendar Year Cap	2010	150,000	163,117
1320a–7h(b)(2)	42 CFR 402.105(h); 42 CFR 403 912(b) & (c).	CMS	Penalty for manufacturer or group purchasing organization knowingly failing to report information required under 42 U.S.C. 1320a–7h(a), relating to physician ownership or investment interests:			
			Minimum	2010	10,000	10,874
			Maximum	2010	100,000	108,745
			Calendar Year Cap	2010	1,000,000	1,087,450

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued

[Effective September 6, 2016]

Citation		HHS agency	Description [2]	Date of last penalty figure or adjustment [3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR [1]					
1320a–7j(h)(3)(A)		CMS	Penalty for an administrator of a facility that fails to comply with notice requirements for the closure of a facility.	2010	100,000	108,745
	42 CFR 488.446(a)(1),(2), & (3).	CMS	Minimum penalty for the first offense of an administrator who fails to provide notice of facility closure.	2010	500	544
			Minimum penalty for the second offense of an administrator who fails to provide notice of facility closure.	2010	1,500	1,631
			Minimum penalty for the third and subsequent offenses of an administrator who fails to provide notice of facility closure.	2010	3,000	3,262
1320a–8(a)(1)		CMS	Penalty for an entity knowingly making a false statement or representation of material fact in the determination of the amount of benefits or payments related to old-age, survivors, and disability insurance benefits, special benefits for certain World War II veterans, or supplemental security income for the aged, blind, and disabled.	1994	5,000	7,954
			Penalty for violation of 42 U.S.C. 1320a–8(a)(1) if the violator is a person who receives a fee or other income for services performed in connection with determination of the benefit amount or the person is a physician or other health care provider who submits evidence in connection with such a determination.	2015	7,500	7,500
1320a–8(a)(3)		CMS	Penalty for a representative payee (under 42 U.S.C. 405(j), 1007, or 1383(a)(2)) converting any part of a received payment from the benefit programs described in the previous civil monetary penalty to a use other than for the benefit of the beneficiary.	2004	5,000	6,229
1320b–25(c)(1)(A)		CMS	Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility.	2010	200,000	217,490
1320b–25(c)(2)(A)		CMS	Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility if such failure exacerbates the harm to the victim of the crime or results in the harm to another individual.	2010	300,000	326,235
1320b–25(d)(2)		CMS	Penalty for a long-term care facility that retaliates against any employee because of lawful acts done by the employee, or files a complaint or report with the State professional disciplinary agency against an employee or nurse for lawful acts done by the employee or nurse.	2010	200,000	217,490
1395b–7(b)(2)(B)	42 CFR 402.105(g)	CMS	Penalty for any person who knowingly and willfully fails to furnish a beneficiary with an itemized statement of items or services within 30 days of the beneficiary's request.	1997	100	147
1395i–3(h)(2)(B)(ii)(I)	42 CFR 488.408(d)(1)(iii)	CMS	Penalty per day for a Skilled Nursing Facility that has a Category 2 violation of certification requirements:			
			Minimum	1987	50	103
			Maximum	1987	3,000	6,188
	42 CFR 488.408(d)(1)(iv)	CMS	Penalty per instance of Category 2 noncompliance by a Skilled Nursing Facility:			
			Minimum	1987	1,000	2,063
			Maximum	1987	10,000	20,628
	42 CFR 488.408(e)(1)(iii)	CMS	Penalty per day for a Skilled Nursing Facility that has a Category 3 violation of certification requirements:			
			Minimum	1987	3,050	6,291
			Maximum	1987	10,000	20,628
	42 CFR 488.408(e)(1)(iv)	CMS	Penalty per instance of Category 3 noncompliance by a Skilled Nursing Facility:			
			Minimum	1987	1,000	2,063
			Maximum	1987	10,000	20,628

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued

[Effective September 6, 2016]

Citation		HHS agency	Description[2]	Date of last penalty figure or adjustment[3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR[1]					
	42 CFR 488.408(e)(2)(ii)	CMS	Penalty per day and per instance for a Skilled Nursing Facility that has Category 3 noncompliance with Immediate Jeopardy:			
			Per Day (Minimum)	1987	3,050	6,291
			Per Day (Maximum)	1987	10,000	20,628
			Per Instance (Minimum)	1987	1,000	2,063
			Per Instance (Maximum)	1987	10,000	20,628
	42 CFR 488.438(a)(1)(i)	CMS	Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the upper range per day:			
			Minimum	1987	3,050	6,291
			Maximum	1987	10,000	20,628
	42 CFR 488.438(a)(1)(ii)	CMS	Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the lower range per day:			
			Minimum	1987	50	103
			Maximum	1987	3,000	6,188
	42 CFR 488.438(a)(2)	CMS	Penalty per instance of a Skilled Nursing Facility that fails to meet certification requirements:			
			Minimum	1987	1,000	2,063
			Maximum	1987	10,000	20,628
1395l(h)(5)(D)	42 CFR 402.105(d)(2)(i)	CMS	Penalty for knowingly, willfully, and repeatedly billing for a clinical diagnostic laboratory test other than on an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395l(i)(6)		CMS	Penalty for knowingly and willfully presenting or causing to be presented a bill or request for payment for an intraocular lens inserted during or after cataract surgery for which the Medicare payment rate includes the cost of acquiring the class of lens involved.	1988	2,000	3,957
1395l(q)(2)(B)(i)	42 CFR 402.105(a)	CMS	Penalty for knowingly and willfully failing to provide information about a referring physician when seeking payment on an unassigned basis.	1989	2,000	3,787
1395m(a)(11)(A)	42 CFR 402.1(c)(4), 402.105(d)(2)(ii).	CMS	Penalty for any durable medical equipment supplier that knowingly and willfully charges for a covered service that is furnished on a rental basis after the rental payments may no longer be made. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395m(a)(18)(B)	42 CFR 402.1(c)(5), 402.105(d)(2)(iii).	CMS	Penalty for any nonparticipating durable medical equipment supplier that knowingly and willfully fails to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395m(b)(5)(C)	42 CFR 402.1(c)(6), 402.105(d)(2)(iv).	CMS	Penalty for any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge for radiologist services. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395m(h)(3)	42 CFR 402.1(c)(8), 402.105(d)(2)(vi).	CMS	Penalty for any supplier of prosthetic devices, orthotics, and prosthetics that knowing and willfully charges for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(a)(11)(A), that is in the same manner as 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued

[Effective September 6, 2016]

Citation		HHS agency	Description [2]	Date of last penalty figure or adjustment [3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR [1]					
1395m(j)(2)(A)(iii)		CMS	Penalty for any supplier of durable medical equipment including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully distributes a certificate of medical necessity in violation of Section 1834(j)(2)(A)(i) of the Act or fails to provide the information required under Section 1834(j)(2)(A)(ii) of the Act.	1994	1,000	1,591
1395m(j)(4)	42 CFR 402.1(c)(10), 402.105(d)(2)(vii).	CMS	Penalty for any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for series billed other than on as assignment-related basis under certain conditions. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(j)(4) and 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395m(k)(6)	42 CFR 402.1(c)(31), 402.105(d)(3).	CMS	Penalty for any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(k)(6) and 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395m(l)(6)	42 CFR 402.1(c)(32), 402.105(d)(4).	CMS	Penalty for any supplier of ambulance services who knowingly and willfully fills or collects for any services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(b)(18)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395u(b)(18)(B)	42 CFR 402.1(c)(11), 402.105(d)(2)(viii).	CMS	Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395u(j)(2)(B)	42 CFR 402.1(c)	CMS	Penalty for any physician who charges more than 125% for a non-participating referral. (Penalties are assessed in the same manner as 42 U.S.C. 1320a–7a(a)).	1996	10,000	15,024
1395u(k)	42 CFR 402.1(c)(12), 402.105(d)(2)(ix).	CMS	Penalty for any physician who knowingly and willfully presents or causes to be presented a claim for bill for an assistant at a cataract surgery performed on or after March 1, 1987, for which payment may not be made because of section 1862(a)(15). (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395u(l)(3)	42 CFR 402.1(c)(13), 402.105(d)(2)(x).	CMS	Penalty for any nonparticipating physician who does not accept payment on an assignment-related basis and who knowingly and willfully fails to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality under 1842(l)(1)(A). (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
[Effective September 6, 2016]

Citation		HHS agency	Description[2]	Date of last penalty figure or adjustment[3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR[1]					
1395u(m)(3)	42 CFR 402.1(c)(14), 402.105(d)(2)(xi).	CMS	Penalty for any nonparticipating physician charging more than $500 who does not accept payment for an elective surgical procedure on an assignment related basis and who knowingly and willfully fails to disclose the required information regarding charges and coinsurance amounts and fails to refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395u(n)(3)	42 CFR 402.1(c)(15), 402.105(d)(2)(xii).	CMS	Penalty for any physician who knowingly, willfully, and repeatedly bills one or more beneficiaries for purchased diagnostic tests any amount other than the payment amount specified by the Act. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395u(o)(3)(B)	42 CFR 414.707(b)	CMS	Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services pertaining to drugs or biologics by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(b)(18)(B) and 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395u(p)(3)(A)		CMS	Penalty for any physician or practitioner who knowingly and willfully fails promptly to provide the appropriate diagnosis codes upon CMS or Medicare administrative contractor request for payment or bill not submitted on an assignment-related basis.	1988	2,000	3,957
1395w–3a(d)(4)(A)	42 CFR 414.806	CMS	Penalty for a pharmaceutical manufacturer's misrepresentation of average sales price of a drug, or biologic.	2003	10,000	12,856
1395w–4(g)(1)(B)	42 CFR 402.1(c)(17), 402.105(d)(2)(xiii).	CMS	Penalty for any nonparticipating physician, supplier, or other person that furnishes physician services not on an assignment-related basis who either knowingly and willfully bills or collects in excess of the statutorily-defined limiting charge or fails to make a timely refund or adjustment. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395w–4(g)(3)(B)	42 CFR 402.1(c)(18), 402.105(d)(2)(xiv).	CMS	Penalty for any person that knowingly and willfully bills for statutorily defined State-plan approved physicians' services on any other basis than an assignment-related basis for a Medicare/Medicaid dual eligible beneficiary. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395w–27(g)(3)(A); 1857(g)(3).	42 CFR 422.760(b); 42 CFR 423.760(b).	CMS	Penalty for each termination determination the Secretary makes that is the result of actions by a Medicare Advantage organization or Part D sponsor that has adversely affected an individual covered under the organization's contract.	1997	25,000	36,794
1395w–27(g)(3)(B); 1857(g)(3).		CMS	Penalty for each week beginning after the initiation of civil money penalty procedures by the Secretary because a Medicare Advantage organization or Part D sponsor has failed to carry out a contract, or has carried out a contract inconsistently with regulations.	1997	10,000	14,718
1395w–27(g)(3)(D); 1857(g)(3).		CMS	Penalty for a Medicare Advantage organization's or Part D sponsor's early termination of its contract.	2000	100,000	136,689

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued

[Effective September 6, 2016]

Citation		HHS agency	Description[2]	Date of last penalty figure or adjustment[3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR[1]					
1395y(b)(3)(C)	42 CFR 411.103(b)	CMS	Penalty for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits not to enroll under a group health plan or large group health plan which would be a primary plan.	1990	5,000	8,908
1395y(b)(5)(C)(ii)	42 CFR 402.1(c)(20); 42 CFR 402.105(b)(2).	CMS	Penalty for any non-governmental employer that, before October 1, 1998, willfully or repeatedly failed to provide timely and accurate information requested relating to an employee's group health insurance coverage.	1998	1,000	1,450
1395y(b)(6)(B)	42 CFR 402.1(c)(21), 402.105(a).	CMS	Penalty for any entity that knowingly, willfully, and repeatedly fails to complete a claim form relating to the availability of other health benefits in accordance with statute or provides inaccurate information relating to such on the claim form.	1994	2,000	3,182
1395y(b)(7)(B)(i)		CMS	Penalty for any entity serving as insurer, third party administrator, or fiduciary for a group health plan that fails to provide information that identifies situations where the group health plan is or was a primary plan to Medicare to the HHS Secretary.	2007	1,000	1,138
1395y(b)(8)(E)		CMS	Penalty for any non-group health plan that fails to identify claimants who are Medicare beneficiaries and provide information to the HHS Secretary to coordinate benefits and pursue any applicable recovery claim.	2007	1,000	1,138
1395nn(g)(5)	42 CFR 411.361	CMS	Penalty for any person that fails to report information required by HHS under Section 1877(f) concerning ownership, investment, and compensation arrangements.	1989	10,000	18,936
1395pp(h)	42 CFR 402.1(c)(23), 402.105(d)(2)(xv).	CMS	Penalty for any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries under certain conditions. (42 U.S.C. 1395(m)(18) sanctions apply here in the same manner, which is under 1395u(j)(2) and 1320a–7a(a)).	1996	10,000	15,024
1395ss(a)(2)	42 CFR 402.1(c)(24), 405.105(f)(1).	CMS	Penalty for any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards after a statutorily defined effective date.	1987	25,000	51,569
1395ss(d)(3)(A)(vi)(II)		CMS	Penalty for someone other than issuer that sells or issues a Medicare supplemental policy to beneficiary without a disclosure statement.	1990	15,000	26,723
			Penalty for an issuer that sells or issues a Medicare supplemental policy without disclosure statement.	1990	25,000	44,539
1395ss(d)(3)(B)(iv)		CMS	Penalty for someone other than issuer that sells or issues a Medicare supplemental policy without acknowledgement form.	1990	15,000	26,723
			Penalty for issuer that sells or issues a Medicare supplemental policy without an acknowledgement form.	1990	25,000	44,539
1395ss(p)(8)	42 CFR 402.1(c)(25), 402.105(e).	CMS	Penalty for any person that sells or issues Medicare supplemental polices after a given date that fail to conform to the NAIC or Federal standards established by statute.	1990	15,000	26,723
	42 CFR 402.1(c)(25), 405.105(f)(2).	CMS	Penalty for any person that sells or issues Medicare supplemental polices after a given date that fail to conform to the NAIC or Federal standards established by statute.	1990	25,000	44,539
1395ss(p)(9)(C)	42 CFR 402.1(c)(26), 402.105(e).	CMS	Penalty for any person that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	1990	15,000	26,723

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued

[Effective September 6, 2016]

Citation		HHS agency	Description[2]	Date of last penalty figure or adjustment[3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR[1]					
	42 CFR 402.1(c)(26), 405.105(f)(3), (4).		Penalty for any person that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	1990	25,000	44,539
1395ss(q)(5)(C)	42 CFR 402.1(c)(27), 405.105(f)(5).	CMS	Penalty for any person that fails to suspend the policy of a policyholder made eligible for medical assistance or automatically reinstates the policy of a policyholder who has lost eligibility for medical assistance, under certain circumstances.	1990	25,000	44,539
1395ss(r)(6)(A)	42 CFR 402.1(c)(28), 405.105(f)(6).	CMS	Penalty for any person that fails to provide refunds or credits as required by section 1882(r)(1)(B).	1990	25,000	44,539
1395ss(s)(4)	42 CFR 402.1(c)(29), 405.105(c).	CMS	Penalty for any issuer of a Medicare supplemental policy that does not waive listed time periods if they were already satisfied under a proceeding Medicare supplemental policy, or denies a policy, or conditions the issuances or effectiveness of the policy, or discriminates in the pricing of the policy base on health status or other specified criteria.	1990	5,000	18,908
1395ss(t)(2)	42 CFR 402.1(c)(30), 405.105(f)(7).	CMS	Penalty for any issuer of a Medicare supplemental policy that fails to fulfill listed responsibilities.	1990	25,000	44,539
1395ss(v)(4)(A)		CMS	Penalty someone other than issuer who sells, issues, or renews a medigap Rx policy to an individual who is a Part D enrollee.	2003	15,000	19,284
			Penalty for an issuer who sells, issues, or renews a Medigap Rx policy who is a Part D enrollee.	2003	25,000	32,140
1395bbb(c)(1)	42 CFR 488.725(c)	CMS	Penalty for any individual who notifies or causes to be notified a home health agency of the time or date on which a survey of such agency is to be conducted.	1987	2,000	4,126
1395bbb(f)(2)(A)(i)	42 CFR 488.845(b)(2)(iii); 42 CFR 488.845(b)(3)–(6); and 42 CFR 488.845(d)(1)(ii).	CMS	Maximum daily penalty amount for each day a home health agency is not in compliance with statutory requirements.	1988	10,000	19,787
	42 CFR 488.845(b)(3)		Penalty per day for home health agency's noncompliance (Upper Range):			
			Minimum	1988	8,500	16,819
			Maximum	1988	10,000	19,787
	42 CFR 488.845(b)(3)(i)		Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in actual harm.	1988	10,000	19,787
	42 CFR 488.845(b)(3)(ii)		Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in potential for harm.	1988	9,000	17,808
	42 CFR 488.845(b)(3)(iii)		Penalty for an isolated incident of noncompliance in violation of established HHA policy.	1988	8,500	16,819
	42 CFR 488.845(b)(4)		Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy, but is directly related to poor quality patient care outcomes (Lower Range):			
			Minimum	1988	1,500	2,968
			Maximum	1988	8,500	16,819
	42 CFR 488.845(b)(5)		Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy and that is related predominately to structure or process-oriented conditions (Lower Range):			
			Minimum	1988	500	989
			Maximum	1988	4,000	7,915
	42 CFR 488.845(b)(6)		Penalty imposed for instance of noncompliance that may be assessed for one or more singular events of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey:			

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued

[Effective September 6, 2016]

Citation		HHS agency	Description [2]	Date of last penalty figure or adjustment [3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR [1]					
			Minimum	1988	1,000	1,979
			Maximum	1988	10,000	19,787
			Penalty for each day of noncompliance (Maximum).	1988	10,000	19,787
	42 CFR 488.845(d)(1)(ii)		Penalty for each day of noncompliance (Maximum).	1988	10,000	19,787
1396b(m)(5)(B)	42 CFR 460.46	CMS	Penalty for PACE organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment:			
			Minimum	1997	15,000	22,077
			Maximum	1997	100,000	147,177
			Penalty for a PACE organization that charges excessive premiums.	1997	25,000	36,794
			Penalty for a PACE organization misrepresenting or falsifying information to CMS, the State, or an individual or other entity.	1997	100,000	147,177
			Penalty for each determination the CMS makes that the PACE organization has failed to provide medically necessary items and services of the failure has adversely affected (or has the substantial likelihood of adversely affecting) a PACE participant.	1997	25,000	36,794
			Penalty for involuntarily disenrolling a participant.	1997	25,000	36,794
			Penalty for discriminating or discouraging enrollment or disenrollment of participants on the basis of an individual's health status or need for health care services.	1997	25,000	36,794
1396r(h)(3)(C)(ii)(I)	42 CFR 488.408(d)(1)(iii)	CMS	Penalty per day for a nursing facility's failure to meet a Category 2 Certification:			
			Minimum	1987	50	103
			Maximum	1987	3,000	6,188
	42 CFR 488.408(d)(1)(iv)	CMS	Penalty per instance for a nursing facility's failure to meet Category 2 certification:			
			Minimum	1987	1,000	2,063
			Maximum	1987	10,000	20,628
	42 CFR 488.408(e)(1)(iii)	CMS	Penalty per day for a nursing facility's failure to meet Category 3 certification:			
			Minimum	1987	3,050	6,291
			Maximum	1987	10,000	20,628
	42 CFR 488.408(e)(1)(iv)	CMS	Penalty per instance for a nursing facility's failure to meet Category 3 certification:	....	....	2,063
			Minimum	1987	1,000	20,628
			Maximum	1987	10,000	
	42 CFR 488.408(e)(2)(ii)	CMS	Penalty per instance for a nursing facility's failure to meet Category 3 certification, which results in immediate jeopardy:	....	....	2,063
			Minimum	1987	1,000	20,628
			Maximum	1987	10,000	
	42 CFR 488.438(a)(1)(i)	CMS	Penalty per day for nursing facility's failure to meet certification (Upper Range):	....	....	6,291
			Minimum	1987	3,050	20,628
			Maximum	1987	10,000	2,063
	42 CFR 488.438(a)(1)(ii)	CMS	Penalty per day for nursing facility's failure to meet certification (Lower Range):			
			Minimum	1987	50	103
			Maximum	1987	3,000	6,188
	42 CFR 488.438(a)(2)	CMS	Penalty per instance for nursing facility's failure to meet certification:			
			Minimum	1987	1,000	2,063
			Maximum	1987	10,000	20,628
1396r(f)(2)(B)(iii)(I)(c)	42 CFR 483.151(b)(2)(iv) and (b)(3)(iii).	CMS	Grounds to prohibit approval of Nurse Aide Training Program—if assessed a penalty in 1819(h)(2)(B)(i) or 1919(h)(2)(A)(ii) of "not less than $5,000" [Not CMP authority, but a specific CMP amount (CMP at this level) that is the triggering condition for disapproval].	1987	5,000	10,314
1396r(h)(3)(C)(ii)(I)	42 CFR 483.151(c)(2)	CMS	Grounds to waive disapproval of nurse aide training program—reference to disapproval based on imposition of CMP "not less than $5,000" [Not CMP authority but CMP imposition at this level determines eligibility to seek waiver of disapproval of nurse aide training program].	1987	5,000	10,314

Civil Monetary Penalty Authorities Administered by HHS Agencies and Penalty Amounts—Continued

[Effective September 6, 2016]

Citation		HHS agency	Description[2]	Date of last penalty figure or adjustment[3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR[1]					
1396t(j)(2)(C)		CMS	Penalty for each day of noncompliance for a home or community care provider that no longer meets the minimum requirements for home and community care:			
			Minimum	1990	1	2
			Maximum	1990	10,000	17,816
1396u–2(e)(2)(A)(i)	42 CFR 438.704	CMS	Penalty for a Medicaid managed care organization that fails substantially to provide medically necessary items and services.	1997	25,000	36,794
			Penalty for Medicaid managed care organization that imposes premiums or charges on enrollees in excess of the premiums or charges permitted.	1997	25,000	36,794
			Penalty for a Medicaid managed care organization that misrepresents or falsifies information to another individual or entity.	1997	25,000	36,794
			Penalty for a Medicaid managed care organization that fails to comply with the applicable statutory requirements for such organizations.	1997	25,000	36,794
1396u–2(e)(2)(A)(ii)	42 CFR 438.704	CMS	Penalty for a Medicaid managed care organization that misrepresents or falsifies information to the HHS Secretary.	1997	100,000	147,177
			Penalty for Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	1997	100,000	147,177
1396u–2(e)(2)(A)(iv)	42 CFR 438.704	CMS	Penalty for each individual that does not enroll as a result of a Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	1997	15,000	22,077
1396u(h)(2)	42 CFR 441, Subpart I	CMS	Penalty for a provider not meeting one of the requirements relating to the protection of the health, safety, and welfare of individuals receiving community supported living arrangements services.	1990	10,000	20,628
1396w–2(c)(1)		CMS	Penalty for disclosing information related to eligibility determinations for medical assistance programs.	2009	10,000	11,002
18041(c)(2)	45 CFR 150.315; 45 CFR 156.805(c).	CMS	Failure to comply with requirements of the Public Health Services Act; Penalty for violations of rules or standards of behavior associated with issuer participation in the Federally-facilitated Exchange. (42 U.S.C. 300gg–22(b)(2)(C)).	1996	100	150
18081(h)(1)(A)(i)(II)	42 CFR 155.285	CMS	Penalty for providing false information on Exchange application.	2010	25,000	27,186
18081(h)(1)(B)	42 CFR 155.285	CMS	Penalty for knowingly or willfully providing false information on Exchange application.	2010	250,000	271,862
18081(h)(2)	42 CFR 155.260	CMS	Penalty for knowingly or willfully disclosing protected information from Exchange.	2010	25,000	27,186
31 U.S.C.:						
1352	45 CFR 93.400(e)	HHS	Penalty for the first time an individual makes an expenditure prohibited by regulations regarding lobbying disclosure, absent aggravating circumstances.	1989	10,000	18,936
			Penalty for second and subsequent offenses by individuals who make an expenditure prohibited by regulations regarding lobbying disclosure:			
			Minimum	1989	10,000	18,936
			Maximum	1989	100,000	189,361
			Penalty for the first time an individual fails to file or amend a lobbying disclosure form, absent aggravating circumstances.	1989	10,000	18,936
			Penalty for second and subsequent offenses by individuals who fail to file or amend a lobbying disclosure form, absent aggravating circumstances:			
			Minimum	1989	10,000	18,936
			Maximum	1989	100,000	189,361
	45 CFR 93, Appendix A	HHS	Penalty for failure to provide certification regarding lobbying in the award documents for all sub-awards of all tiers:			
			Minimum	1989	10,000	18,936
			Maximum	1989	100,000	189,361

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued

[Effective September 6, 2016]

Citation		HHS agency	Description [2]	Date of last penalty figure or adjustment [3]	Pre-inflation penalty ($)	Maximum adjusted penalty ($)
U.S.C.	CFR [1]					
			Penalty for failure to provide statement regarding lobbying for loan guarantee and loan insurance transactions:			
			Minimum	1989	10,000	18,936
			Maximum	1989	100,000	189,361
3801–3812	45 CFR 79.3(a)(1)(iv)	HHS	Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.	1988	5,000	9,894
	45 CFR 79.3(b)(1(ii)		Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.	1988	5,000	9,894

[1] Some HHS components have not promulgated regulations regarding their civil monetary penalty-specific statutory authorities.

[2] The description is not intended to be a comprehensive explanation of the underlying violation; the statute and corresponding regulation, if applicable should be consulted.

[3] Statutory, or non-Inflation Act Adjustment.

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 33. The authority citation for part 147 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

§ 147.200 [Amended]

■ 34. Section 147.200(e) is amended by removing the phrase "not more than $1,000 for" and adding in its place the phrase "not more than $1,000 as adjusted annually under 45 CFR part 102 for".

PART 150—CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS

■ 35. The authority citation for part 150 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92).

§ 150.315 [Amended]

■ 36. Section 150.315 is amended by removing the phrase "may not exceed $100 for" and adding in its place the phrase "may not exceed $100 as adjusted annually under 45 CFR part 102 for".

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 37. The authority citation for part 155 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1332, 1334, 1402, 1411, 1412, 1413, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083).

§ 155.260 [Amended]

■ 38. In § 155.260, paragraph (g) is amended by removing the phrase "not more than $25,000 per" and adding in its place the phrase "not more than $25,000 as adjusted annually under 45 CFR part 102 per".

§ 155.285 [Amended]

■ 39. Amend § 155.285 as follows:

■ a. In paragraph (c)(1)(i), by removing the phrase "of $25,000 for" and adding in its place the phrase "of $25,000 as adjusted annually under 45 CFR part 102 for";

■ b. In paragraph (c)(1)(ii), removing the phrase "of $250,000 for" and adding in its place the phrase "of $250,000 as adjusted annually under 45 CFR part 102 for"; and

■ c. In paragraph (c)(2)(i), removing the phrase "not more than $25,000 per" and adding in its place the phrase "not more than $25,000 as adjusted annually under 45 CFR part 102 per".

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 40. The authority citation for part 156 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1313, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

§ 156.805 [Amended]

■ 41. In § 156.805, paragraph (c) is amended by removing the phrase "$100 for" and adding in its place the phrase "$100 as adjusted annually under 45 CFR part 102 for".

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 42. The authority citation for part 158 continues to read as follows:

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18), as amended.

§ 158.606 [Amended]

■ 43. Section 158.606 is amended by removing the phrase "may not exceed $100 for" and adding in its place the phrase "may not exceed $100 as adjusted annually under 45 CFR part 102 for".

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 44. The authority for part 160 continues to read as follows:

Authority: 42 U.S.C. 1302(a); 42 U.S.C. 1320d–1320d–9; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)); 5 U.S.C. 552; secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279; and sec. 1104 of Pub. L. 111–148, 124 Stat. 146–154.

■ 45. Section 160.404 is amended by revising paragraph (a) to read as follows:

§ 160.404 Amount of a civil money penalty.

(a) The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section, and §§ 160.406, 160.408, and 160.412. These amounts were adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment

Act of 1990, (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, (section 701 of Pub. L. 114–74), and appear at 45 CFR part 102. These amounts will be updated annually and published at 45 CFR part 102.

* * * * *

Subtitle B—Regulations Related to Public Welfare

Chapter II—Office of Family Assistance (Assistance Programs), Administration for Children and Families, Department of Health and Human Services

PART 303—STANDARDS FOR PROGRAM OPERATIONS

■ 46. The authority citation for part 303 continues to read as follows:

Authority: 42 U.S.C. 651 through 658, 659a, 660, 663, 664, 666, 667, 1302, 1396a(a)(25), 1396b(d)(2), 1396b(o), 1396b(p), and 1396(k).

■ 47. Section 303.21 is amended by revising paragraph (f) to read as follows:

§ 303.21 Safeguarding and disclosure of confidential information.

* * * * *

(f) Penalties for unauthorized disclosure. Any disclosure or use of confidential information in violation of 42 U.S.C. 653(l)(2) and implementing regulations shall be subject to:

(1) Any State and Federal statutes that impose legal sanctions for such disclosure; and

(2) The maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under 42 U.S.C. 653(l)(2) as shown in the table at 45 CFR 102.3.

Dated: July 21, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–18680 Filed 9–2–16; 8:45 am]

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